

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022032Orig1s024

Trade Name: Omeprazole

Generic or Proper Name: Omeprazole

Sponsor: Dexcel Pharma Technologies Ltd.

Approval Date: March 6, 2015

Indication: Treats frequent heartburn (occurs 2 or more days a week)

CENTER FOR DRUG EVALUATION AND RESEARCH

022032Orig1s024

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

APPROVAL LETTER



NDA 022032/S-024

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S.
Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated March 15, 2014, received March 18, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

We acknowledge receipt of your amendments dated March 17 and 30, May 16, July 18, October 15, December 12, 2014, and January 30, 2015.

The October 15, 2014 submission constituted a complete response to our September 29, 2014 action letter.

This "Prior Approval" sNDA proposes to add a Wildberry Mint flavor to the already-approved, original marketed drug product.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

- For all cartons, under the **Directions** section of the Drug Facts label, unbold the statement, "Swallow whole. Do not chew, crush or suck tablets." Please submit this change as part of your final printed labeling (FPL).

LABELING

Submit FPL, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labels as listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable;

Labels submitted on December 12, 2014:

- Wildberry Mint 14-count immediate container (blister)
- Wildberry Mint 14-count immediate container (bottle)
- Wildberry Mint 14-count inner blister carton
- Wildberry Mint 14-, 28- and 42-count blister cartons
- Wildberry Mint 14-, 28- and 42-count bottle cartons
- Wildberry Mint 14-, 28- and 42-count blister and bottle carton PDP peel-off coupon labels
- Wildberry Mint “FDA Approved” 14-, 28- and 42-count blister and bottle carton labels
- Wildberry Mint “Bonus pack! 14 Free” 28- and 42-count blister and bottle labels
- Wildberry Mint “BONUS! 14 FREE” 28- and 42-count blister and bottle labels
- Wildberry Mint “14 FREE” 28- and 42-count blister and bottle labels
- Wildberry Mint “28 + 14 FREE” 42-count blister and bottle carton labels
- Wildberry Mint “Triple Pack Three 14-day courses of treatment” 42-count blister and bottle labels
- Wildberry Mint “3 Pack Three 14-day courses of treatment” 42-count bottle label
- Wildberry Mint “Value Pack 3-14 Tablet Bottles” 42-count bottle label

Labels submitted on January 30, 2015:

- Wildberry Mint “3 Pack Three 14-day courses of treatment” 42-count blister label
- Wildberry Mint “Value Pack 3-14 Tablet Cartons” 42-count blister label

The FPL should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022032/S-024.**” Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes

Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have questions, contact Jeffrey Buchanan, Regulatory Health Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
03/06/2015

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

OTHER ACTION LETTERS



NDA 022032/S-024

COMPLETE RESPONSE

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S.
Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated March 15, 2014, received March 18, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

We acknowledge receipt of your amendments dated March 17 and 30, May 16, and July 18, 2014.

This "Prior Approval" labeling supplement proposes to add (b) (4) flavors (b) (4) (b) (4) to the already-approved, original marketed drug product.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

- Section 3.2.P.2 states that (b) (4) was used to develop the flavored product, Omeprazole Delayed Release Tablets, 20 mg. Clarify the proposed design space or the (b) (4) in this change.
- Only one flavor (b) (4) formulation is included in the submission. Provide the formulation for the (b) (4) flavor. In addition, clarify if the formulation in the submission is for (b) (4)
- Provide stability data for the (b) (4) flavor under long-term, intermediate and accelerated conditions.
- Only one set of dissolution profile data of three pivotal batch Nos. B.N. BY150813, 160813, and 170813 was provided, which were all coated with the same flavor, (b) (4)

(b) (4) Clarify if this batch data is for the (b) (4)
(b) (4). In order to support the approval of this supplemental new drug application, provide comparative dissolution profile data to support the (b) (4) flavor.

LABELING

- Provide data supporting your proposed labeling for the new flavors as follows:
 - Data which demonstrate that consumers experience a flavor coating containing menthol as (b) (4)
 - Label comprehension study results
 - Data to support a treatment effect claim of heartburn relief such as (b) (4)

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the supplemental application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA Guidance for Industry, "Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before approval of this supplemental application.

If you have questions, contact Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
09/29/2014

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

LABELING

This label may not be the latest approved by FDA.
For labeling information, please visit <https://www.fda.gov>

Coated with wildberry mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd.
10 Hakidma Street,
Yokneam, 20692, Israel

Coated with wildberry mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd.
10 Hakidma Street,
Yokneam, 20692, Israel

Coated with wildberry mint flavor
Omeprazole DR Tablets 20mg
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Coated with wildberry mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd.
10 Hakidma Street,
Yokneam, 20692, Israel

Swallow whole.
Do not chew, crush, or suck tablets.
One 14-day course of treatment
Do not take for more than 14 days
or more often than every 4 months
unless directed by a doctor.
40100 00 X1

Coated with wildberry mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd.
10 Hakidma Street,
Yokneam, 20692, Israel

Coated with wildberry mint flavor
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Coated with wildberry mint flavor
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Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd.
10 Hakidma Street,
Yokneam, 20692, Israel



= No Print Area

This label may not be the latest approved by FDA.
 Labeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Bottle Label)



ACTUAL SIZE



150% FOR REVIEW ONLY

MODIFIED FORMAT

TYPE SIZES:

- TITLE: 8 pt Helvetica Neue 77 Bold Cond Oblique
- HEADINGS: 7 pt Helvetica Neue 77 Bold Cond Oblique
- SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
- TEXT: 6 pt Helvetica Neue 57 Cond
- LEADING: 6.0 pt
- BULLETS: 5 pt Square with 2 M'S spacing between statements
- TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
- HEAVY LINES: 1.0 pt
- HAIRLINES: 0.5 pt

This label may not be the latest approved by FDA.
abeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling

NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets Peel Off Coupon

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

NDC 00000-000-00

SAVE \$X NOW!
On This Purchase

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

14 Tablets

: 40374 FA C01

One 14-day course of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of
14 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. **RETAILER:** This coupon will be redeemable for face value on specified products (plus a handling fee) providing the terms of this offer have been complied with. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCH, PO Box 980036, El Paso, TX 79998-0036

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



**Omeprazole
Delayed Release
Tablets 20 mg
14 Count**

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Bottle Carton)

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

NDC 0000-000-00

Treats **Frequent Heartburn!**
 Occurring **2 Or More Days a Week**

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg
Acid Reducer
 SWALLOW - DO NOT CHEW

14 Tablets
 One 14-day course of treatment
 1 BOTTLE INSIDE

Drug Facts (continued)

- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

Drug Facts (continued)

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other Information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive Ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- if overweight, lose weight ■ Quit smoking

Drug Facts

Active Ingredient (in each tablet) Purpose
 Omeprazole 20 mg.....Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clobazam (blood-thinning medicines)

LOT NO. **CODE AREA**

EXP.

: 40125 FA C1

MODIFIED FORMAT

TYPE SIZES:
 TITLE: 8 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 7 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 7 pt Helvetica Neue 57 Cond
 HEADINGS: 7 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.0/6.5 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Bottle Carton)

000000000

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

FDA Approved

DIE CUT WINDOW

Treats **Frequent Heartburn!**
 Occurring **2 Or More Days a Week**

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

14 Tablets
 One 14-day course of treatment
1 BOTTLE INSIDE

Coated with **Wildberry Mint Flavor**

LOT NO.
EXP.
: 401D5 FA CBP1-F

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000000000

000000000

Drug Facts (continued)

- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- **swallow whole. Do not chew, crush, or suck tablets.**

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**

Drug Facts (continued)

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other Information

- read the directions and warnings before use
- Keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive Ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight ■ Quit smoking

Drug Facts

Active Ingredient (in each tablet) Purpose
 Omeprazole 20 mg.....Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clobazam (blood-thinning medicines)

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 HAIRLINES: 0.5 pt

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Labeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Bottle Carton) Peel Off Coupon

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 0000-000-00

Treats **Frequent** Heartburn!
Occurring 2 Or More Days a Week

 Treat My Heartburn .com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

Coated with **Wildberry Mint Flavor**

14 Tablets

One 14-day course of treatment

1 BOTTLE INSIDE

: 40135 FA CP1

BACK PANEL

SAVE \$X NOW!

Omeprazole Delayed Release Tablets 20 mg 14 Count

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of 14 COUNT SIZE "Store Brand" Omeprazole Delayed Release Tablets 20 mg

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) providing the terms of this offer have been complied with. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-transferable. Coupons cannot be combined. Mail properly handled coupon to: NCA, PO Box 880036, El Paso, TX 88588-0036



0 00000 00000 0

12-9-14

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets



Drug Facts (continued)
Inactive Ingredients
benzyl alcohol, camphor, carmellose, hypromellose acetate, sucrose, lactose monohydrate, menthol, modified starch, monothalamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

**Omeprazole Delayed
Release Tablets 20mg**

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer

Purpose
Acid reducer

Use
● Treats frequent heartburn (occurs 2 or more days a week)
● Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing, food, vomiting with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
Heartburn with lightheadedness, sweating or dizziness chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness frequent wheezing, paroxysmal with heartburn unexplained weight loss nausea or vomiting stomach pain

Ask a doctor or pharmacist before use if you are taking warfarin, digoxin or other oral-thinning medicines prescription antifungal or anti-fungal medicines azapam (anxiety medicine) dexamethasone (heart medicine) baclofen (muscle relaxant) or other prescription antiretrovirals (medicines for HIV infection)

Directions
For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days
It may take 1 to 4 days for full effect so me people get complete relief of symptoms within 24 hours
14-Day Course of the abatement
swallow 1 tablet with a glass of water before eating in the morning
do not take more than 1 tablet a day
do not use for more than 14 days unless directed by your doctor
do not chew, crush, or suck tablets.
Repeat 14-Day Courses (if needed)
You may repeat a 14-day course every 4 months do not take more than 14 days or more often than every 4 months unless directed by a doctor
Children under 18 years of age ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
Read the directions and warnings before use
Keep the carton. It contains important information.
Store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)
Stop use and ask a doctor if your heartburn continues or worsens
You need to take more than 1 course of treatment every 4 months
You need to take more than 1 course of treatment every 4 months
If pregnant or breast-feeding, ask a health professional if you get diarrhea

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Manufactured by:
Dexxel Pharma Technologies Ltd.,
10 Heiklima Street, Yokneam, 20692, Israel

Made in Israel

CODE AREA

40130 FA C3

**Omeprazole Delayed
Release Tablets 20mg**



**Safety Feature -
Do not use if
printed tablet
blister unit is
open or torn.**

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



NDC 00000-000-00

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor


28 Tablets

Two 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 and 7.0 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt


**Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets**



Questions or comments? 1-800-779-9260

Inactive Ingredients
benzyl alcohol, camphor, carnauba wax, FD&C blue #2, hydroxypropyl methylcellulose, hypromellose acetate succinate, lactose monohydrate, mannitol, modified starch, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Drug Facts (continued)



Other Information

- Read the directions and warnings before use. Keep the carton. It contains important information.
- Store at 20°-25°C (68°-77°F) and protect from moisture.

Directions

- For adults 18 years of age and older: Take 1 tablet every day (every 24 hours), every day for 14 days.
- For children under 18 years of age: Ask a doctor. Heartburn in children may sometimes be caused by a reflux condition.

Warnings

- Do not use if you have trouble or pain swallowing food, vomiting with blood, or black stools. These may be signs of a serious condition. See your doctor.
- Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

Use

- Best frequent heartburn (occurs 2 or more days a week) not relieved for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.

Active ingredient (in each tablet)
Omeprazole 20 mg, Acid reducer

Purpose
Acid reducer

Drug Facts

Warnings

- Heartburn with lightheadedness, sweating or dizziness
- Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- Heart chest pain
- Heartburn with lightheadedness, sweating or dizziness
- Headache, dizziness, or lightheadedness
- Stomach pain
- Diarrhea or constipation
- Ask a doctor or pharmacist before use if you are taking:
 - Warfarin, digoxin, or clozapine (blood-thinning medicines)
 - Aspirin, ibuprofen, or other pain relievers
 - Antibiotics
 - Antifungal medicines
 - Antidepressants
 - Anticancer medicines
 - Anticoagulants
 - Antipsychotics
 - Antiviral medicines
 - Antibiotics
 - Antifungal medicines
 - Antidepressants
 - Anticancer medicines
 - Anticoagulants
 - Antipsychotics
 - Antiviral medicines

Other Information

- Read the directions and warnings before use. Keep the carton. It contains important information.
- Store at 20°-25°C (68°-77°F) and protect from moisture.

Manufactured by:
Cexxel Pharma Technologies Ltd.
10 Haldima Street, Yokneam, 20692, Israel

CODE AREA

: 40130 FA CBP1-F



Omeprazole Delayed Release Tablets 20mg

Safety Feature - Do not use if printed tablet blister unit is open or torn.

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed

- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

FDA Approved NDC 00000-000-00



Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 Tablets

Two 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued)
8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 and 7.0 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets

Drug Facts (continued)
Inactive Ingredients
 benzyl alcohol, camphor, croscarmellose, hypromellose acetate, sucrose, lactose monohydrate, menthol, modified starch, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-779-9260

Drug Facts (continued)

Warnings
 Allergic alert: Do not use if you are allergic to omeprazole.
 Do not use if you have trouble or pain swallowing food, vomiting with blood or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have:
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting
 ■ stomach pain

Use
 ■ Beets frequent heartburn (occurs 2 or more days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
 Allergic alert: Do not use if you are allergic to omeprazole.
 Do not use if you have trouble or pain swallowing food, vomiting with blood or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have:
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting
 ■ stomach pain

Other information
 ■ Read the directions and warnings before use
 ■ Keep the carton. It contains important information.
 ■ Store at 20-25°C (68-77°F) and protect from moisture.
 ■ Children under 18 years of age ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
 ■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.
 ■ You may repeat a 14-day course every 4 months.
 ■ Repeated 14-day courses (if needed)
 ■ Do not use for more than 14 days unless directed by your doctor.
 ■ Swallow whole. Do not chew, crush, or suck tablets.
 ■ Do not take more than 1 tablet a day.
 ■ Take every day for 14 days.
 ■ Swallow 1 tablet with a glass of water before eating in the morning.
 ■ 14-Day Course of Treatment
 ■ Relief of symptoms within 24 hours
 ■ It may take 1 to 4 days for full effect, so no people get complete relief of symptoms within 24 hours.
 ■ For adults 18 years of age and older
 ■ This product is to be used once a day (every 24 hours), every day for 14 days.
 ■ Directions
 ■ Stop use and ask a doctor if:
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea
 ■ you are pregnant or breast-feeding, ask a health professional before use.
 ■ Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Manufactured by:
 Dexcel Pharma Technologies Ltd.
 10 Heikims Street, Yokneam, 20892, Israel

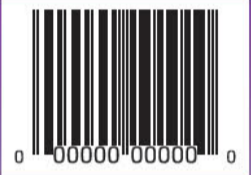
Made in Israel

CODE AREA

: 40130 FA CBP1-D

**Omeprazole Delayed
 Release Tablets 20mg**

**Omeprazole Delayed
 Release Tablets 20mg**



Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Safety Feature -
 Do not use if
 printed tablet
 blister unit is
 open or torn.**

Bonus Pack! 14 Free

NDC 0000-000-00



Treats **Frequent Heartburn!**
 Occurring **2 Or More Days a Week**

**Omeprazole Delayed
 Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 ~~14~~ Tablets

Two ~~One~~ 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 8 pt Helvetica Neue 57 Cond
 HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 and 7.0 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

This label may not be the latest approved by FDA.
Labeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets Peel Off Coupon

FRONT PANEL

Peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 00000-000-00

Treats **Frequent** Heartburn!
Occurring **2 Or More Days a Week**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 Tablets

40130 FA CP1

Two 14-day courses of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of
28 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) providing the terms of this offer have been complied with. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCH, PO Box 880036, El Paso, TX 88588-0036



Omeprazole Delayed Release Tablets 20 mg 28 Count

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton)

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Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or clostrazolol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearoyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

00000000

NDC 0000-000-00

Treats **Frequent Heartburn!**
 Occurring **2 Or More Days a Week**

DIE CUT WINDOW **DIE CUT WINDOW**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 Tablets
 Two 14-day courses of treatment
2 BOTTLES INSIDE

Coated with **Wildberry Mint Flavor**

LOT NO.
 EXP.
 : 40136 FA C1

CODE AREA

Drug Facts

Active ingredient	Purpose
Omeprazole 20 mg	Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 8 pt Helvetica Neue 57 Cond

HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton)



Drug Facts (continued)

- Ask a doctor or pharmacist before use if you are taking
- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
 - prescription antifungal or anti-yeast medicines
 - diazepam (anxiety medicine)
 - digoxin (heart medicine)
 - tacrolimus (immune system medicine)
 - prescription antiretrovirals (medicines for HIV infection)

- Stop use and ask a doctor if**
- your heartburn continues or worsens
 - you need to take this product for more than 14 days
 - you need to take more than 1 course of treatment every 4 months
 - you get diarrhea

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-719-9260

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel

Manufactured by:
Dexel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Drug Facts

Active ingredient Purpose (in each tablet)
Omeprazole 20 mg.....Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.

- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond

HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond

TEXT: 6 pt Helvetica Neue 57 Cond

LEADING: 6.5 pt

BULLETS: 5 pt Square with 2 M'S spacing between statements

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton)

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Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking
 ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ diazepam (anxiety medicine)
 ■ digoxin (heart medicine)
 ■ tacrolimus (immune system medicine)
 ■ prescription antiretrovirals (medicines for HIV infection)

Stop use and ask a doctor if
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
 ■ for adults 18 years of age and older
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
 ■ swallow 1 tablet with a glass of water before eating in the morning
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor

■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)
Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel
 Manufactured by:
Dexel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn
 ■ Do not lie flat or bend over after eating
 ■ Do not wear tight-fitting clothing around the stomach
 ■ Do not eat before bedtime
 ■ Raise the head of your bed

■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 ■ Eat slowly and avoid big meals
 ■ If overweight, lose weight
 ■ Quit smoking

Bonus Pack! 14 Free

DIE CUT WINDOW **DIE CUT WINDOW**

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW **28 14 Tablets**

Coated with **Wildberry Mint Flavor** Two ~~One~~ 14-day courses of treatment **2 BOTTLES INSIDE**

LOT NO. **CODE AREA**

EXP. : 40106 FA CBP1-D

MDC 0000-000-00

Drug Facts
Active ingredient Purpose (in each tablet)
 Omeprazole 20 mg.....Acid reducer

Use
 ■ treats frequent heartburn (occurs 2 or more days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting ■ stomach pain

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STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 8 pt Helvetica Neue 57 Cond
 HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton)

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Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or clostrazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Safety Feature - Do not use if printed seal under cap is broken or missing.

Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd,
 10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Bonus! 14 Free

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg

Acid Reducer



Coated with
Wildberry Mint Flavor

SWALLOW - DO NOT CHEW

28 14 Tablets

Two ~~One~~ 14-day courses of treatment

2 X BOTTLES INSIDE

NDC 0000-000-000

Drug Facts

Active ingredient Purpose (in each tablet)
 Omeprazole 20 mg.....Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain



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LOT NO.

EXP.

: 401D6 FA CBP1-E

CODE AREA

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton)

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Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking
 ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ diazepam (anxiety medicine)
 ■ digoxin (heart medicine)
 ■ tacrolimus (immune system medicine)
 ■ prescription antiretrovirals (medicines for HIV infection)
Stop use and ask a doctor if ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
 ■ for adults 18 years of age and older
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
 ■ swallow 1 tablet with a glass of water before eating in the morning
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ swallow whole. Do not chew, crush, or suck tablets.
Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
 ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)
Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture
Inactive ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate
Questions or comments?
 1-800-719-9260
Safety Feature - Do not use if printed seal under cap is broken or missing.
 Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn
 ■ Do not lie flat or bend over after eating
 ■ Do not wear tight-fitting clothing around the stomach
 ■ Do not eat before bedtime
 ■ Raise the head of your bed
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 ■ Eat slowly and avoid big meals
 ■ If overweight, lose weight
 ■ Quit smoking

14 FREE DIE CUT WINDOW

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg
Acid Reducer
SWALLOW - DO NOT CHEW
 28 Tablets
 Two 14-day courses of treatment
 2 BOTTLES INSIDE

Drug Facts
Active ingredient Purpose (in each tablet)
 Omeprazole 20 mg.....Acid reducer
Use
 ■ treats frequent heartburn (occurs 2 or more days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
Allergy alert: Do not use if you are allergic to omeprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting ■ stomach pain

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LOT NO.
EXP.
 : 401D6 FA CBP1-B

CODE AREA

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

This label may not be the latest approved by FDA. Labeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
28 Tablets (Bottle Carton) Peel Off Coupon

FRONT PANEL

peel off coupon
Instant Redeemable Coupon - Expires XX-XX-XX
SAVE \$X NOW!
On This Purchase

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

NDC 0000-000-00

 TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

 SWALLOW - DO NOT CHEW **28 Tablets**
Two 14-day courses of treatment
2 BOTTLES INSIDE

Coated with **Wildberry Mint Flavor**

: 40106 FA C P1

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of 28 COUNT SIZE "Store Brand" Omeprazole Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. **RETAILER:** This coupon will be redeemable for face value on specified products (plus a handling fee) providing the terms of this offer have been complied with. Cash value 1/100th of one cent. Limit one coupon per customer. **Do Not Double.** Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCH, PO Box 880036, El Paso, TX 88588-0036

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.




Omeprazole Delayed Release Tablets 20 mg 28 Count

12-9-14

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets

Omeprazole Delayed
Release Tablets 20 mg



CODE AREA

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg.....acid reducer

Use
■ Treats frequent heartburn (occurs 2 or more days a week)
■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
■ Do not use if you are allergic to omeprazole with food, or blood or black stools. These may be signs of a serious condition. See your doctor.
■ Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

■ Heartburn with high fevers, sweating or dizziness
■ Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders or lightheadedness
■ Request wheezing, particularly with heartburn
■ Nausea or vomiting
■ Unexplained weight loss
■ Stomach pain

■ Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clopidogrel (blood-thinning medicines) or prescription antifungal or anti-yeast medicines
■ Zepaxim (antibiotic medicine)
■ Digoxin (heart medicine)
■ Tacrolimus (immune system medicine)
■ Prescription antiretroviral (medicines for HIV infection)


Other information
■ Read the directions and warnings before use
■ Keep the carton. It contains important information.
■ Store at 20-25°C (68-77°F) and protect from moisture

Directions
■ For adults 18 years of age and older
■ This product is to be used once a day (every 24 hours), everyday for 14 days
■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
■ 14-Day Course of Treatment
■ Swallow 1 tablet with a glass of water before eating in the morning
■ Take every day for 14 days
■ Do not take more than 1 tablet a day
■ Do not use for more than 14 days unless directed by your doctor
■ Swallow whole. Do not chew, crush, or suck tablets.
■ Repeat 14-Day Courses if needed
■ You may repeat a 14-day course every 4 months
■ Do not take more than 14 days or more often than every 4 months unless directed by a doctor
■ Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

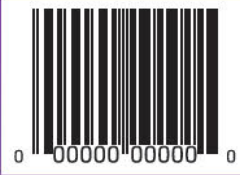
Inactive ingredients (continued)
Dibutyltin dilaurate, camphor, camphor wax, FD&C blue #2, hydroxyamine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthyl, modified starch, monobenzothiazolone, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

Manufactured by:
Cesca Pharma Technologies Ltd.
10 Hakdama Street, Yokneam, 20602, Israel



40155 FA CBP-1-F




**Omeprazole Delayed
Release Tablets 20mg**

Safety Feature -
Do not use if printed tablet blister unit is open or torn.

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

FDA Approved NDC 00000-000-00




Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



42 Tablets
Three 14-day courses of treatment

Coated with **Wildberry Mint Flavor**

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STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 and 7.0 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets

Omeprazole Delayed Release Tablets 20mg

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer

Use
■ Treats frequent heartburn (occurs 2 or more days a week) take 1 to 4 days for full effect
■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
Heartburn with high blood pressure, sweating or dizziness chest pain or shoulder pain with shortness of breath, sweating pain spreading to arms, neck or shoulders, or lightheadedness frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain

Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clopidogrel or anti-thrombotic medicines, prescription antifungal or anti-yeast medicines, diazepam (anxiety medicine), digoxin (heart medicine), tacrolimus (immune system medicine) or prescription antiretroviral (medicines for HIV infection)

Other information
■ Read the directions and warnings before use
■ Keep the carton. It contains important information.
■ Store at 20-25°C (68-77°F) and protect from moisture

Directions
■ For adults 18 years of age and older
■ This product is to be used once a day (every 24 hours), every day for 14 days
■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
■ Swallow 1 tablet with a glass of water before eating in the morning
■ Take every day for 14 days
■ Do not take more than 1 tablet a day
■ Do not use for more than 14 days unless directed by your doctor
■ Swallow whole. Do not chew, crush, or suck tablets.
Repeat 14-Day Courses (if needed)
■ You may repeat a 14-day course every 4 months
■ Do not take more than 14 days or more often than every 4 months unless directed by a doctor
■ Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)
Stop use and ask a doctor if your heartburn continues or worsens or you need to take this product for more than 14 days
You need to take more than 1 course of treatment every 4 months
You get diarrhea
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center in right away: (1-800-222-1222)

CODE AREA

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Omeprazole Delayed Release Tablets 20mg

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Safety Feature - Do not use if printed tablet blister unit is open or torn.

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Do not wear tight-fitting clothing around the stomach
- Eat slowly and avoid big meals
- Do not eat before bedtime
- If overweight, lose weight
- Raise the head of your bed
- Quit smoking

Bonus Pack! 14 Free NDC 00000-000-00



Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



42 ~~28~~ Tablets

Coated with **Wildberry Mint Flavor** Three ~~Two~~ 14-day courses of treatment

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STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 and 7.0 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets**

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Warnings

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

heartburn with nighttime aches, swelling or dizziness chest pain or shoulder pain with shortness of breath, sweating pain spreading to arms, neck or shoulders, or lightheadedness frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain

Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clostazed (blood-thinning medicines), diazepam (anxiety medicine), dexamethasone (steroid), or other medicines.

lactation (milk) (some systemic medicines) prescription antiretroviral medicines for HIV infection)

CODE AREA

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

swallow 1 tablet with a glass of water before eating in the morning.

take every day for 14 days.

do not take more than 1 tablet a day.

do not use for more than 14 days unless directed by your doctor.

swallow whole. Do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)

you may repeat a 14-day course every 4 months.

do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

read the directions and warnings before use.

keep the carton. It contains important information.

store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Warnings

Do not use if you are allergic to omeprazole.

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

heartburn with nighttime aches, swelling or dizziness chest pain or shoulder pain with shortness of breath, sweating pain spreading to arms, neck or shoulders, or lightheadedness frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain

Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clostazed (blood-thinning medicines), diazepam (anxiety medicine), dexamethasone (steroid), or other medicines.

lactation (milk) (some systemic medicines) prescription antiretroviral medicines for HIV infection)

CODE AREA

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

swallow 1 tablet with a glass of water before eating in the morning.

take every day for 14 days.

do not take more than 1 tablet a day.

do not use for more than 14 days unless directed by your doctor.

swallow whole. Do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)

you may repeat a 14-day course every 4 months.

do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

read the directions and warnings before use.

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Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

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14-Day Course of Treatment

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Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

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Other information

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store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

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Repeat 14-Day Courses (if needed)

you may repeat a 14-day course every 4 months.

do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

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Other information

read the directions and warnings before use.

keep the carton. It contains important information.

store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

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Repeat 14-Day Courses (if needed)

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Other information

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keep the carton. It contains important information.

store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

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you may repeat a 14-day course every 4 months.

do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

read the directions and warnings before use.

keep the carton. It contains important information.

store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Directions

For adults 18 years of age and older this product is to be used once a day (every 24 hours), every day.

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment

swallow 1 tablet with a glass of water before eating in the morning.

take every day for 14 days.

do not take more than 1 tablet a day.

do not use for more than 14 days unless directed by your doctor.

swallow whole. Do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)

you may repeat a 14-day course every 4 months.

do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

read the directions and warnings before use.

keep the carton. It contains important information.

store at 20-25°C (68-77°F) and protect from moisture.

Manufactured by:
Dexel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique

TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued) 8 pt Helvetica Neue 57 Cond

HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond

TEXT: 6 pt Helvetica Neue 57 Cond

LEADING: 6.5 and 7.0 pt

BULLETS: 5 pt Square with 2 M'S spacing between statements

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets



Drug Facts (continued)
Inactive ingredients
 benzylalcohol, camphor, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, maltitol, modified starch, monobenzylamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

**Omeprazole Delayed
 Release Tablets 20mg**

Drug Facts (continued)

Warnings
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
 Headburn with lightheadedness, sweating or dizziness
 Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders or lightheadedness
 Frequent chest pain
 Frequent wheezing, particularly with heartburn
 Unexplained weight loss
 Nausea or vomiting
 Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clostrazol (blood-thinning medicines) or prescription anti-biopsy or anti-yeast medicines
 Do not take with grapefruit juice

Use
 Omeprazole 20 mg (each tablet) Acid reducer

Purpose
 Treats frequent heartburn (occurs 2 or more days a week) and prevents heartburn (relief of heartburn; this drug may take 1 to 4 days for full effect)

Directions
 For adults 18 years of age and older
 This product is to be used once a day (every 24 hours), every day for 14 days
 It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
 14-Day Course of Treatment
 Swallow 1 tablet with a glass of water before eating in the morning
 Do not take more than 1 tablet a day
 Do not use for more than 14 days unless directed by your doctor
 Swallow whole. Do not chew, crush, or suck tablets.
 Repeated 14-Day Courses (if needed)
 You may repeat a 14-day course every 4 months
 Do not take for more than 14 days or more often than every 4 months unless directed by a doctor
 Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
 Read the directions and warnings before use
 Keep the carton it contains important information
 Store at 20-25°C (68-77°F) and protect from moisture

Manufactured by:
Dexcel Pharma Technologies Ltd.
 10 Haskins Street, Yokneam, 20692, Israel

Made in Israel

CODE AREA

40155 FA C1



**Omeprazole Delayed
 Release Tablets 20mg**

**Safety Feature -
 Do not use if
 printed tablet
 blister unit is
 open or torn.**

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

14 FREE



Treats **Frequent Heartburn!**
 Occurring 2 Or More Days a Week

**Omeprazole Delayed
 Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued) 8 pt Helvetica Neue 57 Cond
 HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
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 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 and 7.0 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Active ingredient (in each tablet)
 Omeprazole 20 mg.....Acid reducer

Use
 ■ Treats frequent heartburn (occurs 2 or more days a week)
 ■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or body or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

■ Heartburn with nighttime awakenings, sweating or dizziness
 ■ Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
 ■ Request chest pain
 ■ Request wheezing, particularly with heartburn
 ■ Request weight loss
 ■ Request vomiting
 ■ Stomach pain

Ask a doctor or pharmacist before use if you are taking warfarin, clopidogrel or clostaz (blood-thinning medicines), prescription antifungal or anti-fungal medicines, diazepam (anxiety medicine), digoxin (heart medicine), tacrolimus (immune system medicine), prescription and over-the-counter (OTC) medicines, or other drugs.

Other information
 ■ Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
 ■ Do not take more than 14 days or more often than every 4 months unless directed by a doctor.
 ■ Do not take form more than 14 days or more often than every 4 months unless directed by a doctor.


Directions
 ■ For adults 18 years of age and older
 ■ This product is to be used once a day (every 24 hours), every day for 14 days
 ■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
 ■ 14-day course of treatment
 ■ Swallow 1 tablet with a glass of water before eating in the morning
 ■ Do not take more than 14 days unless directed by your doctor
 ■ Swallow whole. Do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)
 ■ You may repeat a 14-day course every 4 months
 ■ Do not take form more than 14 days or more often than every 4 months unless directed by a doctor.

■ Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

CODE AREA

Omeprazole Delayed Release Tablets 20mg



28 + 14 FREE NDC 00000-000-00

Safety Feature - Do not use if printed tablet blister unit is open or torn.

Tips for Managing Heartburn


- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



42 Tablets

Coated with **Wildberry Mint Flavor**

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
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 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 and 7.0 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Club Size)

Manufactured by:
CevaPharma Technologies Ltd.
10 Heklidna Street, Yokneam, 20892, Israel

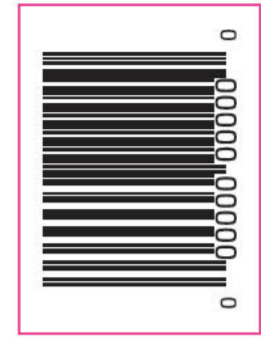
Made in Israel

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Safety Feature - Do not use if printed tablet blister unit is open or torn.

Drug Facts Active ingredient (in each tablet) Omeprazole 20 mg, Acid reducer	Use ■ Treats frequent heartburn (occurs 2 or more days a week) ■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings Do not use if you are allergic to omeprazole	Warnings Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition. ■ Heartburn with lightheadedness, sweating or dizziness ■ Chest pain or shoulder pain with shortness of breath, sweating, fainting, or dizziness, or fainting ■ Frequent chest pain ■ Frequent wheezing, particularly with heartburn ■ Unexplained weight loss ■ Nausea or vomiting ■ Stomach pain
Directions ■ For adults 18 years of age and older ■ This product is to be used once a day (every 24 hours), every day for 14 days ■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours	Other information ■ Children under 18 years of age: ask a doctor. Heartburn in children 4 months unless directed by a doctor ■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ You may repeat a 14-day course every 4 months ■ Repeated 14-Day Courses (if needed) ■ Swallow whole. Do not chew, crush, or suck tablets. ■ Do not use for more than 14 days unless directed by your doctor ■ Do not take more than 1 tablet a day ■ Do not take more than 1 tablet a day ■ Take every day for 14 days ■ Swallow 1 tablet with a glass of water before eating in the morning
Inactive ingredients beryllium hydroxide, calcium carbonate, FD&C blue #2, iron oxide, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate	Questions or comments? 1-800-719-9260

Drug Facts Active ingredient (in each tablet) Omeprazole 20 mg, Acid reducer	Use ■ Treats frequent heartburn (occurs 2 or more days a week) ■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings Do not use if you are allergic to omeprazole	Warnings Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition. ■ Heartburn with lightheadedness, sweating or dizziness ■ Chest pain or shoulder pain with shortness of breath, sweating, fainting, or dizziness, or fainting ■ Frequent chest pain ■ Frequent wheezing, particularly with heartburn ■ Unexplained weight loss ■ Nausea or vomiting ■ Stomach pain
Directions ■ For adults 18 years of age and older ■ This product is to be used once a day (every 24 hours), every day for 14 days ■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours	Other information ■ Children under 18 years of age: ask a doctor. Heartburn in children 4 months unless directed by a doctor ■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ You may repeat a 14-day course every 4 months ■ Repeated 14-Day Courses (if needed) ■ Swallow whole. Do not chew, crush, or suck tablets. ■ Do not use for more than 14 days unless directed by your doctor ■ Do not take more than 1 tablet a day ■ Do not take more than 1 tablet a day ■ Take every day for 14 days ■ Swallow 1 tablet with a glass of water before eating in the morning
Inactive ingredients beryllium hydroxide, calcium carbonate, FD&C blue #2, iron oxide, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate	Questions or comments? 1-800-719-9260



CODE AREA
This Code Area Box Must Be Printed in Black or Darkest Color. Laser Coding Removes the Ink and Becomes White.

NDC 00000-000-00

3 PACK Three 14-day courses of treatment



Treats **Frequent** Heartburn!
Occurring **2 Or More** Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with **Wildberry Mint Flavor**

42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 13 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 10 pt Helvetica Neue 77 Bold Cond Oblique (continued)
SUBHEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
TEXT: 8 pt Helvetica Neue 57 Cond
LEADING: 8.7 pt
BULLETS: 7 pt Square with 2 M'S spacing between statements
TELEPHONE #: 8 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 2.0 pt
HAIRLINES: 0.5 pt

PRINT OUT at 65%

This label may not be the latest approved by FDA.
Labeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling

NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets Peel Off Coupon

FRONT PANEL

Peel Off
Coupon

Instant Redeemable Coupon - Expires XX-XX-XX

NDC 00000-000-00

SAVE \$X NOW!
On This Purchase

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment

: 40155 FA CP1

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of
42 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable
per purchase. RETAILER: This coupon will
be redeemable for face value on specified
products (plus a handling
fee) providing the terms of
this offer have been complied
with. Cash value 1/100th of
one cent. Limit one coupon
per customer. Do Not Double.
Coupons are non-reproducible.
Coupons cannot be combined.
Mail properly handled coupons
to: NCH, PO Box 880036, El
Paso, TX 88588-0036



**Omeprazole
Delayed Release
Tablets 20 mg
42 Count**

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

000000000



Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....**Purpose**
Acid reducer

Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain

Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel or clostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus (immune system medicine)
■ prescription antiretrovirals (medicines for HIV infection)

Drug Facts (continued)

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 20692, Israel

NDC 0000-000-00

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer



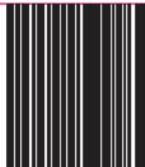
Coated with
Wildberry Mint Flavor

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Safety Feature -
Do not use if printed seal under cap is broken or missing.



000000000



CODE AREA

LOT NO.

EXP.

: 401D7 FA C1

STANDARD FORMAT

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TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
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HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)



<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</p> <p>Purpose</p> <p>Use</p> <ul style="list-style-type: none"> treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> had heartburn over 3 months. This may be a sign of a more serious condition. heartburn with lightheadedness, sweating or dizziness chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness frequent chest pain frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> warfarin, clopidogrel or cilostazol (blood-thinning medicines) prescription antifungal or anti-yeast medicines diazepam (anxiety medicine) digoxin (heart medicine) tacrolimus (immune system medicine) prescription antiretrovirals (medicines for HIV infection) 	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> your heartburn continues or worsens you need to take this product for more than 14 days you need to take more than 1 course of treatment every 4 months you get diarrhea <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p>Directions</p> <ul style="list-style-type: none"> for adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> swallow 1 tablet with a glass of water before eating in the morning take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor swallow whole. Do not chew, crush, or suck tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <ul style="list-style-type: none"> read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F) and protect from moisture 	<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9260</p> <p>Made in Israel</p> <p>Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam, 20692, Israel</p>	<p>Tips for Managing Heartburn</p> <ul style="list-style-type: none"> Do not lie flat or bend over after eating Do not wear tight-fitting clothing around the stomach Do not eat before bedtime Raise the head of your bed Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables Eat slowly and avoid big meals If overweight, lose weight Quit smoking <p>FDA Approved</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p> <p>DIE CUT WINDOW DIE CUT WINDOW DIE CUT WINDOW</p> <p>Omeprazole Delayed Release Tablets 20mg</p> <p>Acid Reducer</p> <p>SWALLOW - DO NOT CHEW</p> <p>42 Tablets</p> <p>Three 14-day courses of treatment 3 BOTTLES INSIDE</p> <p>Safety Feature - Do not use if printed seal under cap is broken or missing.</p>
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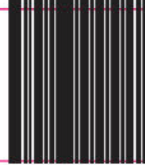
STANDARD FORMAT

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HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
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LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer	Stop use and ask a doctor if	<ul style="list-style-type: none"> your heartburn continues or worsens you need to take this product for more than 14 days you need to take more than 1 course of treatment every 4 months you get diarrhea
Use		Directions	
<ul style="list-style-type: none"> treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect 		<ul style="list-style-type: none"> for adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 	
Warnings		14-Day Course of Treatment	
<p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> had heartburn over 3 months. This may be a sign of a more serious condition. heartburn with lightheadedness, sweating or dizziness chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness frequent chest pain frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> warfarin, clopidogrel or cilostazol (blood-thinning medicines) prescription antifungal or anti-yeast medicines diazepam (anxiety medicine) digoxin (heart medicine) tacrolimus (immune system medicine) prescription antiretrovirals (medicines for HIV infection) 		<ul style="list-style-type: none"> swallow 1 tablet with a glass of water before eating in the morning take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor swallow whole. Do not chew, crush, or suck tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>Other information</p> <ul style="list-style-type: none"> children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F) and protect from moisture 	

Drug Facts (continued)

Inactive ingredients
benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Bonus Pack! 14 Free Treats Frequent Heartburn! Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg

Acid Reducer



SWALLOW - DO NOT CHEW 42 ~~28~~ Tablets

Three ~~Two~~ 14-day courses of treatment 3 ~~2~~ BOTTLES INSIDE



LOT NO.
EXP.
: 401D7 FA C8P1-D

CODE AREA

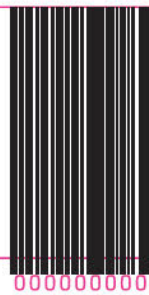
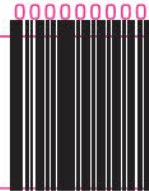
Safety Feature - Do not use if printed seal under cap is broken or missing.

STANDARD FORMAT

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TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique (continued)
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
 NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
 42 Tablets (Bottle Carton)



Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection)	
Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

Drug Facts (continued)
Inactive ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd.,
 10 Hakidma Street, Yokneam, 20692, Israel

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Bonus! 14 Free Treats Frequent Heartburn!
Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg



Acid Reducer


 Coated with Wildberry Mint Flavor

SWALLOW - DO NOT CHEW 42 ~~28~~ Tablets
 Three ~~Two~~ 14-day courses of treatment
 3 ~~2~~ BOTTLES INSIDE



LOT NO.
 EXP.
 : 401D7 FA CBP1-E

CODE AREA

Safety Feature -
 Do not use if printed seal under cap is broken or missing.

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued): 8 pt Helvetica Neue 57 Cond
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SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)**

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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clostrazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection)	
Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.	
Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

Drug Facts (continued)
Inactive ingredients
benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd,
10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

14 FREE

DIE CUT WINDOW **DIE CUT WINDOW** **DIE CUT WINDOW**

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Coated with **Wildberry Mint Flavor**

0 000000 000000 0

LOT NO.

EXP.

40107 FA CBP1-B

CODE AREA

Safety Feature - Do not use if printed seal under cap is broken or missing.

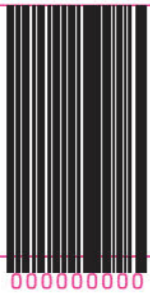


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STANDARD FORMAT

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BULLETS: 5 pt Square with 2 M'S spacing between statements
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HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
 NDA 22-032
 Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
 42 Tablets (Bottle Carton)



Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection)	
Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.	
Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

Drug Facts (continued)
Inactive ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd,
 10 Haikidda Street, Yokneam, 20692, Israel

NDC 00000-000-00

28 + 14 FREE

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

DIE CUT WINDOW **DIE CUT WINDOW** **DIE CUT WINDOW**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE

Coated with Wildberry Mint Flavor

TreatMyHeartburn.com

0 000000 000000 0

Safety Feature -
 Do not use if printed seal under cap is broken or missing.

LOT NO.
 EXP.
 : 401D7 FA CBP1-C

CODE AREA

STANDARD FORMAT

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 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
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 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

<p>Drug Facts Active ingredient (in each tablet) Omeprazole 20 mg.....Purpose Acid reducer</p>	<p>Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea</p>	<p>Drug Facts (continued) Inactive ingredients benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium steryl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p>	<p>Tips for Managing Heartburn</p> <ul style="list-style-type: none"> ■ Do not lie flat or bend over after eating ■ Do not wear tight-fitting clothing around the stomach ■ Do not eat before bedtime ■ Raise the head of your bed ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables ■ Eat slowly and avoid big meals ■ If overweight, lose weight ■ Quit smoking
<p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p>	<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p>	<p>Questions or comments? 1-800-719-9260</p>	<p>Triple Pack Three 14-day courses of treatment</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p>
<p>Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p>	<p>Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</p>	<p>Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture</p>	<p>DIE CUT WINDOW DIE CUT WINDOW DIE CUT WINDOW</p> <p>TreatMyHeartburn.com</p>
<p>Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection)</p>	<p>14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets.</p> <p>Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>	<p>Made in Israel Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam, 20692, Israel</p>	<p>Omeprazole Delayed Release Tablets 20mg</p> <p>Acid Reducer</p> <p>SWALLOW - DO NOT CHEW</p> <p>42 Tablets</p> <p>Three 14-day courses of treatment 3 BOTTLES INSIDE</p> <p>Coated with Wildberry Mint Flavor</p>
<p>0000000000</p>	<p>0000000000</p>	<p>0000000000</p>	<p>LOT NO.</p> <p>EXP.</p> <p>: 40137 FA CBP1-G</p> <p>CODE AREA</p> <p>0000000000</p>

Safety Feature - Do not use if printed seal under cap is broken or missing.

STANDARD FORMAT

TYPE SIZES:
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 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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3 PACK Three 14-day courses of treatment

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

DIE CUT WINDOW **DIE CUT WINDOW** **DIE CUT WINDOW**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment

3 BOTTLES INSIDE

LOT NO.

EXP.

: 403D7 FA CBP1-A

000000000

CODE AREA

Drug Facts

Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer	Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection)	Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture		

Drug Facts (continued)
Inactive ingredients
 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd.,
 10 Hakidma Street, Yokneam, 20692, Israel

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Safety Feature - Do not use if printed seal under cap is broken or missing.

STANDARD FORMAT

TYPE SIZES:
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 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Proposed Draft Labeling
 NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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Drug Facts
Active ingredient (in each tablet) Omeprazole 20 mg.....**Purpose** Acid reducer

Use
 ■ treats frequent heartburn (occurs 2 or more days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting
 ■ stomach pain
Ask a doctor or pharmacist before use if you are taking
 ■ warfarin, clopidogrel or clostazol (blood-thinning medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ diazepam (anxiety medicine)
 ■ digoxin (heart medicine)
 ■ tacrolimus (immune system medicine)
 ■ prescription antiretrovirals (medicines for HIV infection)

Drug Facts (continued)
Stop use and ask a doctor if
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea
If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
 ■ for adults 18 years of age and older
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
 ■ swallow 1 tablet with a glass of water before eating in the morning
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ swallow whole. Do not chew, crush, or suck tablets.
Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
 ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)
Inactive ingredients
 benzyl alcohol, carmine, camauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd.
 10 Hakidma Street, Yokneam, 20692, Israel

Value Pack!
 3-14 Tablet Bottles

NDC 0000-000-00

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

DIE CUT WINDOW **DIE CUT WINDOW** **DIE CUT WINDOW**

Safety Feature -
 Do not use if printed seal under cap is broken or missing.

Omeprazole Delayed Release Tablets 20mg



Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE

Coated with Wildberry Mint Flavor



LOT NO.

EXP.

: 40107 FA CBP1-J

CODE AREA

STANDARD FORMAT
TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 8 pt Helvetica Neue 57 Cond
 HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

This label may not be the latest approved by FDA.
abeling information, please visit <https://www.fda.gov>

Proposed Draft Labeling

NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton) Peel Off Coupon

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 0000-000-00

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**



Coated with
Wildberry Mint Flavor

: 401D7 FA CP1

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets
Three 14-day courses of treatment

3 BOTTLES INSIDE



Omeprazole Delayed Release Tablets 20mg

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your next purchase of
42 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable
per purchase. RETAILER: This coupon will
be redeemable for face value on specified

products (plus a handling
fee) providing the terms
of this offer have been
complied with. Cash value
1/100th of one cent. Limit
one coupon per customer.
Do Not Double. Coupon is
non-reproducible. Coupons
cannot be combined. Mail
properly handled coupons
to: MCF, PO Box 886036,
El Paso, TX 79868-0036

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.



Omeprazole Delayed Release Tablets 20 mg 42 Count

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

LABELING REVIEW(S)

Labeling Review for Omeprazole Delayed Release Tablets, 20 mg

SUBMISSION DATES:	March 14, May 16, July 18, October 15, and December 12, 2014, and January 30, 2015
NDA/SUBMISSION TYPE:	22-032 S-024
ACTIVE INGREDIENTS:	Omeprazole, 20mg
DOSAGE FORMS:	Tablet, Delayed Release
SPONSOR:	Dexcel Pharma Technologies Limited Mary-Anne D'Esposito, M.Sc. US Agent Lachman Consultant Services, Inc. 1600 Stewart Avenue Westbury, New York 11590 516-222-6222
REVIEWER:	Mary R. Vienna, R.N., M.H.A., DNDP/ODE IV
TEAM LEADER:	Steven Adah, Ph.D., DNDP/ODE IV
PROJECT MANAGER	Jeffrey A. Buchanan, DNDP/ODE IV

I. BACKGROUND

Approved labeling includes a 14-count immediate container (blister), 14-count immediate container (bottle), 14-count inner blister carton, 14-, 28- and 42-count blister cartons, and 14-, 28- and 42-count bottle cartons. Approved statements on the blister and bottle cartons include:

- “FDA Approved”
- “Bonus Pack! 14 Free”
- “14 FREE”
- “BONUS! 14 FREE!”
- “Value Pack 3-14 Tablet Cartons/Bottles”
- “28 + 14 FREE”
- “Triple Pack Three 14-day courses of treatment” and
- “3 Pack Three 14-day courses of treatment”

Additionally, a Principal Display Panel (PDP) peel-off coupon is approved for the 14-, 28- and 42-count blister cartons, and the 14-, 28- and 42-count bottle cartons.

The July 18, 2014 submission included a label comprehension study and a sensory evaluation of the proposed flavor statements in response to our information request of April 25, 2014.

A Complete Response letter was issued for the supplement on September 29, 2014. See the July 17, 2014 label review for supplement background and Complete Response deficiencies.

The sponsor submitted a complete response on October 15, 2014 [REDACTED] (b) (4) clarified that the [REDACTED] (b) (4) is the only proposed flavor for this supplement.

An information request was sent to the sponsor on December 1, 2014, requesting a correction to the flavor name that accurately reflects the sensory evaluation data. It was noted that the proposed name of the coating as [REDACTED] (b) (4) was misleading, as study participants described the flavor of the placebo tablet as both berry and mint, with an aftertaste that was more strongly mint than berry.

The sponsor submitted revised labeling on December 12, 2014, in response to our December 1, 2014 information request. The submission withdrew the proposed [REDACTED] (b) (4) labels and submitted proposed “Wildberry Mint Flavor” labels in their place. An information request was sent to the sponsor on January 28, 2015 requesting revised labeling for two 42-count blister cartons with illegible Drug Fact labels. The sponsor submitted revised labeling on January 30, 2015, in response to our information request.

Labeling reviewed is the draft labeling submitted on December 12, 2014 and January 30, 2015, and is compared to the labeling approved with S-021 on August 16, 2013, which is the most recently approved labeling and Drug Facts label.

Submitted Labeling S-024	Representative of Following SKUs	Date Submitted
14-count blister (immediate container) Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count bottle (immediate container) Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count inner carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count blister carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count bottle carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count blister carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014

Submitted Labeling S-024	Representative of Following SKUs	Date Submitted
14-count bottle carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count blister carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
14-count bottle carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count bottle carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count bottle carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count bottle carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton with “Bonus pack! 14 Free”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count bottle carton with “Bonus pack! 14 Free, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton with “14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count bottle carton with “14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
28-count blister carton with “BONUS! 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014

Submitted Labeling S-024	Representative of Following SKUs	Date Submitted
28-count bottle carton with “BONUS! 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “FDA Approved”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with PDP peel-off coupon, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “Bonus pack! 14 Free”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “Bonus pack! 14 Free”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “BONUS! 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “BONUS! 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014

Submitted Labeling S-024	Representative of Following SKUs	Date Submitted
42-count blister carton with “Value Pack 3-14 Tablet Cartons”, Wildberry Mint flavor	none	March 14, 2014 Revised January 30, 2015
42-count bottle carton with “Value Pack 3-14 Tablet Cartons”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “28 + 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “28 + 14 FREE”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “Triple Pack Three 14-day courses of treatment”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count bottle carton with “Triple Pack Three 14-day courses of treatment”, Wildberry Mint flavor	none	March 14, 2014 Revised December 12, 2014
42-count blister carton with “3 Pack Three 14-day courses of treatment”, Wildberry Mint flavor	none	March 14, 2014 Revised January 30, 2015
42-count bottle carton with “3 Pack Three 14-day courses of treatment”, Wildberry Mint flavor	None	March 14, 2014 Revised December 12, 2014

II. REVIEWER’S COMMENTS

A. Tablets, delayed-release (14-, 28-, 42-count blister cartons)

i. Inner Carton (14-count blister) and Outer Carton Label Outside Drug Facts

- a. The statement “SWALLOW – DO NOT CHEW” appears under the statement of identity. The 14-, 28- and 42-count PDP peel off coupon labels are changed also.

Comment: this is acceptable.

- b. The flavor statement “Coated with Wildberry Mint Flavor” appears on the lower left portion of the PDP under a graphic of a purple colored tablet. The 14-, 28- and 42-count PDP peel off coupon labels are changed also.

Comment: this is acceptable.

ii. Outer Carton Drug Facts Label**a. Directions**

Under the **Directions** section, [REDACTED] (b) (4) revised to read “Swallow whole. Do not chew, crush or suck tablets” and the statement has been bolded.

Comment: this is acceptable, but it is unnecessary to bold the statement. The Medical Officer’s review of the first flavored omeprazole tablet (NDA 21-229, S-022, Clinical Review of June 2, 2011) recommends that bolding is not required, and the statement is not bolded in the approved Drug Facts label of the Prilosec flavored tablet. For consistency with approved labeling, inform the sponsor that the statement should be unbolded as a minor editorial change.

b. Inactive ingredients

The list of inactive ingredients has been changed to reflect the new formulation for the flavored supplement. Refer to the July 24, 2014, CMC review.

Comment: this is acceptable.

iii. Immediate Container (Blister) Label**a.** [REDACTED] (b) (4)

Comment: this is acceptable.

b. The statement [REDACTED] (b) (4) at the center of the 14-count blister card has been changed to read “Do not chew, crush or suck tablets”.

Comment: this is acceptable.

B. Tablets, delayed-release (14-, 28-, 42-count bottle cartons)**i. Outer Carton Label Outside Drug Facts**

See comments found under section II.A.i.a. and b.

ii. Outer Carton Drug Facts Label

See comments found under section II.A.ii.a. and b.

iii. Immediate Container (Bottle) Label

a. The statement “SWALLOW – DO NOT CHEW” appears under the statement of identity.

Comment: this is acceptable.

b. The flavor statement “Coated with Wildberry Mint Flavor” appears on the lower left portion of the PDP under a graphic of a purple colored tablet.

Comment: this is acceptable.

III. RECOMMENDATIONS

Issue an **APPROVAL** letter to the sponsor for the submitted Omeprazole Delayed Release tablets, 20 mg labeling and request final printed labeling. Request that the sponsor submit final printed labeling (FPL) identical to the following labels submitted on December 12, 2014:

- Wildberry Mint 14-count immediate container (blister)
- Wildberry Mint 14-count immediate container (bottle)
- Wildberry Mint 14-count inner blister carton
- Wildberry Mint 14-, 28- and 42-count blister cartons
- Wildberry Mint 14-, 28- and 42-count bottle cartons
- Wildberry Mint 14-, 28- and 42-count blister and bottle carton PDP peel-off coupon labels
- Wildberry Mint “FDA Approved” 14-, 28- and 42-count blister and bottle carton labels
- Wildberry Mint “Bonus pack! 14 Free” 28- and 42-count blister and bottle labels
- Wildberry Mint “BONUS! 14 FREE” 28- and 42-count blister and bottle labels
- Wildberry Mint “14 FREE” 28- and 42-count blister and bottle labels
- Wildberry Mint “28 + 14 FREE” 42-count blister and bottle carton labels
- Wildberry Mint “Triple Pack Three 14-day courses of treatment” 42-count blister and bottle labels
- Wildberry Mint “3 Pack Three 14-day courses of treatment” 42-count bottle label
- Wildberry Mint “Value Pack 3-14 Tablet Bottles” 42-count bottle label

and the following labels submitted on January 30, 2015:

- Wildberry Mint “3 Pack Three 14-day courses of treatment” 42-count blister label
- Wildberry Mint “Value Pack 3-14 Tablet Cartons” 42-count blister label

For consistency with other approved OTC flavored omeprazole products, we recommend the following minor editorial change:

For all cartons, under the **Directions** section of the Drug Facts label, unbold the statement “Swallow whole. Do not chew, crush or suck tablets”. Please submit this change as part of your final printed labeling.

IV. SUBMITTED LABELING

The labels on the remaining pages of this labeling review were submitted and evaluated in this labeling review:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R VIENNA
02/04/2015

STEVEN A ADAH
02/05/2015

Labeling Review for Omeprazole Delayed Release Tablets, 20 mg

SUBMISSION DATES: March 14 and May 16, 2014

NDA/SUBMISSION TYPE: 22-032 S-024

ACTIVE INGREDIENTS: Omeprazole, 20mg

DOSAGE FORMS: Tablet, Delayed Release

SPONSOR: Dexcel Pharma Technologies Limited
Mary-Anne D’Esposito, M.Sc.
US Agent Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590
516-222-6222

TEAM LEADER: Ruth E. Scroggs, Pharm.D., DNRD/ODE IV

PROJECT MANAGER Rebecca McKnight, ONDQA
Jeffrey A. Buchanan, DNCE/ODE IV

I. BACKGROUND

NDA 22-032 is a 505(b)(2) application approved December 04, 2007, for the treatment of frequent heartburn (occurring more than two times per week). The reference-listed drug (RLD) product for the basis of the 505(b)(2) submission is Prilosec OTC, NDA 21-229, approved on June 20, 2003. Approved labeling includes a 14-count immediate container (blister), 14-count immediate container (bottle), 14-count inner blister carton, 14-, 28- and 42-count blister cartons, and 14-, 28- and 42-count bottle cartons.

Supplement-024, submitted on proposes add (b) (4) flavors (b) (4) to the already-approved original marketed approved drug product. Marketing of the product will involve use of a series of already approved promotional statements (see Table 1 for list of submitted labeling pieces and the associated statements). The submitted labeling also includes

The May 16, 2014 submission was a response to our April 25, 2014 information request for the following:

The sponsor’s May 16, 2014 response provides the following information:

Request 1. Data that demonstrate that consumers experience a flavor coating containing menthol as (b) (4) flavor.

The sponsor states in the cover letter that in order to complete the response, Dexcel commits to perform a sensory evaluation using a panel of judges which will evaluate the final formulation and to submit the results prior to the supplement goal date of July 18, 2014. The sensory evaluation study's objective will be to provide data that member panelists recognized berry flavor in addition to menthol. Performing sensory evaluation using panelists has two main advantages:

Request 2: Request for labeling comprehension data

The sponsor states in response to the Information Request, that Dexcel commits to conduct a label comprehension study and to submit the results to the FDA prior to the supplement goal date of July 18, 2014.

Request 3: Data to support a treatment effect claim of heartburn relief such as (b) (4) Refer the sponsor to Guidance for Industry – Patient-Reported Outcome Measures: Use Medical Product Development to Support Labeling Claims.

Response 3:

In order to complete the response, Dexcel commits to perform a sensory evaluation using a panel of judges who will evaluate the final formulation and to submit the results prior to the supplement goal date of July 18, 2014.

Labeling reviewed is the draft labeling submitted on March 14, 2014 and is compared to the labeling approved with S-021 on August 16, 2013.

Table 1 describes the 82 pieces of labeling submitted on March 14, 2014, for review for both of the proposed flavors, (b) (4)

Table 1	
14-count inner carton for blisters	(b) (4)
14-count blister card	(b) (4)
14-, 28-, 42-count carton for blisters	(b) (4)
14-, 28-, 42-count carton for bottles	(b) (4)
14-count inner carton for bottles	(b) (4)
14-count bottle label	(b) (4)
The following primary display panels are requested with and without promotional flags as follows:	
Absence of promotional flags for a set of 14-,28-, and 42-count blister and bottle carton labels	
Comment: This is acceptable.	
To the upper left corners of the primary display panels, the following 8 types of promotional flags are added. These promotions have been previously approved	

for the original flavor labeling, however are new proposed labeling in this application (new flavor variants)

- “FDA Approved: 14-, 28-, and 42-count blister and bottle carton labels
- “14 FREE” : 28- and 42-count blister carton labels
- “28 + 14 FREE: 42-count blister carton label
- “Bonus pack!” 14 Free: 28- and 42-count blister and bottle carton labels
- “Triple Pack Three 14-day courses of treatment: 42-counter blister and bottle carton labels
- “Bonus! 14 Free”: 28- and 42-count blister and bottle carton labels
- Peel-off coupon “



- 14-, 28-, 42- count blister and bottle carton labels
- “Value Pack! 3-14 Tablet Cartons “or “Value Pack! 3-14 Tablet Bottles”: 42-count blister and bottle carton labels

Comment: These promotions are acceptable.


II. REVIEWER’S COMMENTS

*See table 1 for a description of the proposed promotional flags and coupons

A. Tablets, delayed-release (14-, 28-, 42-count blister carton)

i. Inner Carton and Outer Carton Label *Outside Drug Facts

a.

Blister carton- 14 Tablets ✖	
	<p>Currently Approved in NDA NDC 0000-000-00 Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p> <p>Omeprazole Delayed Release Tablets 20mg Acid Reducer</p>
Graphic presentation of tablet (PDP)	 <p>14 Tablets One 14-day course of treatment</p>

(b) (4)

* for this review, the 14-count represents the 28-ct carton (28 Tablets, Two 14-day courses of treatment) and the 42-ct carton, Three 14-day courses of treatment)

ii. Outer Carton Drug Facts Label

a. Directions

Directions	<p><i>Directions</i></p> <ul style="list-style-type: none">- for adults 18 years of age and older- this product is to be used once a day (every 24 hours), every day for 14 days- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none">- swallow 1 tablet with a glass of water before eating in the morning- take every day for 14 days- do not take more than 1 tablet a day- do not use for more than 14 days unless directed by your doctor- swallow whole. Do not chew or crush tablets- children under 18 years of age: ask a doctor. <p>Heartburn in children may sometimes be caused by a serious condition.</p>	(b) (4)
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b. Inactive ingredients

List of Inactive ingredients	<p><i>Inactive ingredients</i> camauba wax, ferric¹ oxide red, ferric oxide yellow¹, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol¹, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate</p>	(b) (4)
------------------------------	--	---------

(b) (4)

c. Other Information

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Comment: Storage conditions are determined by ONDQA.

iii. Immediate Container (Blister) Label

Wildberry is shown for comparison.

(b) (4)


Comparison of Labeling Blister (Wildberry Flavor)		
Prilosec OTC® (NDA 021229)		
<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>
<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>
<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Swallow whole. Do not chew, crush, or suck tablets.</p> <p>One 14-day course of treatment</p> <p>Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.</p> <p>99828041</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>
<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>
<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>	<p>Coated with WILDBERRY FLAVOR</p> <p>Prilosec OTC®</p> <p>1 omeprazole magnesium delayed-release tablet 20.6 mg / Acid reducer</p> <p>Push tablet through printed side.</p> <p>Dist. By Procter& Gamble Cincinnati, OH 45202</p>

(b) (4)

B. Tablets, delayed-release (14-*, 28-, 42-count bottle carton)

*See table 1 for a description of the proposed promotional flags and coupons

i. Outer Carton Label *Outside Drug Facts


Bottle carton- 14 Tablets *		(b) (4)
	Currently Approved in NDA	
	NDC 0000-000-00 Treats Frequent Heartburn! Occurring 2 Or More Days a Week	
	<i>DIE CUT WINDOW</i>	
	Omeprazole Delayed Release Tablets 20mg Acid Reducer	
Graphic presentation of tablet (PDP)	 14 Tablets One 14-day course of treatment 1 BOTTLE INSIDE	

* In this review, the 14-ct represents the 28-ct carton (28 Tablets, Two 14-day courses of treatment, 2 bottles inside) and the 42-ct carton (42 Tablets, Three 14-day courses of treatment, 3 bottles inside)

ii. Outer Carton Drug Facts Label

See comments found under section II.A.ii. a., b., and c.

iii. Immediate Container (Bottle) Label

Bottle Label		(b) (4)
Currently Approved in NDA		
NOT FOR RESALE		
Treats Frequent Heartburn! Occurring 2 Or More Days a Week Omeprazole Delayed Release Tablets 20mg Acid Reducer		
 14 Tablets One 14-day course of treatment		
		(b) (4)

III. RECOMMENDATIONS

Issue an **COMPLETE RESPONSE** letter to the sponsor for the submitted labeling.

- Please inform the sponsor that we have not received its final response to our request for information.

Request 1. Data that demonstrate that consumers experience a flavor coating containing menthol as [REDACTED] ^{(b) (4)} flavor.

Request 2: Request for labeling comprehension study results

Request 3: Data to support a treatment effect claim of heartburn relief such as [REDACTED] ^{(b) (4)}

- ONDQA has a separate information request to send to the sponsor, please convey those to the sponsor.

IV. SUBMITTED LABELING

The submitted labeling (82 separate PDFs, of March 14, 2014, have a combined file size of 40 megabytes, therefore the labeling is not attached to this review because of the large file size.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

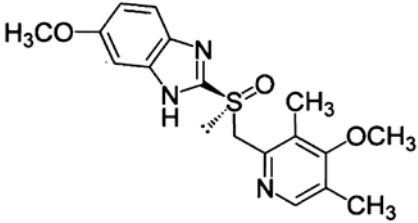
RUTH E SCROGGS
07/17/2014

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1. ORGANIZATION:	2. NDA Number: 22-032
3. Name and Address of Applicant (City & State) Dexcel Pharma Technologies 1 Dexcel Street Or Akiva, Israel 3060000		4. Supplement(s) Number(s) Date(s) S-024 3/14/14
5. Drug Name Omeprazole	6. Nonproprietary Name Omeprazole	7. Amendments - Dates
8. Supplement Provides For: the addition of flavored, purple colored Omeprazole Delayed Release Tablets, 20 mg.		
9. Pharmacological Category For the treatment of frequent heartburn (occurring two or more days a week).	10. How Dispensed Rx	11. Related NDAs
12. Dosage Form(s) Delayed Release Tablets	13. Potency 20 mg	
14. Chemical Name and Structure: <u>5-methoxy-2-[[[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole.</u>		
 <p>Molecular Formula: C₁₇H₁₉ N₃O₃S Molecular weight: 345.42</p>		15. Records/Reports Current Yes <input checked="" type="checkbox"/> No Reviewed Yes No <input checked="" type="checkbox"/>
16. Comments: This is a PA supplement proposes to add flavored Omeprazole Delayed Release Tablets, 20 mg. Dexcel intends to market both the flavored and unflavored Omeprazole Delayed Release Tablets, 20 mg. The stability data presented in this submission demonstrate that the proposed flavored Omeprazole Delayed Release Tablets, 20 mg and the current unflavored Omeprazole Delayed Release Tablets, 20 mg are comparable and equivalent.		
17. Conclusions and Recommendations: The supplement cannot be approved in present from due to the deficiencies listed below. The following Information Request should be communicated to the applicant.		
<ul style="list-style-type: none"> Section 3.2.P.2 states that (b) (4) was used to develop the flavored product, Omeprazole Delayed Release Tablets, 20 mgt. Clarify what is the proposed design space or the (b) (4) in this change. Only one flavor (b) (4) formulation is included in the submission. Provide formulation for the (b) (4) flavor. In addition, clarify if the formulation in the submission is for (b) (4) Provide stability data for the (b) (4) flavor under long term, intermediate and accelerated conditions. Only one set of dissolution profile data of three pivotal batch Nos. B.N. BY150813, 160813, and 170813 was provided, which were all coated with the same flavor, (b) (4) 		

(b) (4) Clarify if this batch data is for the (b) (4)
In order to support the approval of this PAS-024, provide to the Agency for review
another the set of comparative dissolution profile data to support the (b) (4) flavor.

A 'Complete Response' is requested from the applicant. Issue a 'CR' letter.

18. Reviewer:

Name: Kris Raman, Ph.D.
Sr. CMC Reviewer

Signature:

Date Completed: 7/14/2014,
revised 7/21/2014

REVIEW NOTES

This PA supplement provides for the addition of flavored, purple colored Omeprazole Delayed Release Tablets, 20 mg. Dexcel Pharma Technologies Ltd. intends to market both the flavored and unflavored Omeprazole Delayed Release Tablets, 20 mg.

Description of the Drug Product Current vs. Proposed

Unflavored Drug Product: Omeprazole Delayed Release Tablets, 20 mg are brownish, capsule shaped film coated tablets, with a debossment "20" on one side.

Flavored Drug Product: Omeprazole Delayed Release Tablets, 20 mg are purple, capsule shaped film coated tablets, with a berry like odor, with a debossment "20" on one side.

Table 1 provides the comparison of compositions of unflavored and flavored Omeprazole Delayed Release Tablets, 20 mg.

Table 1: Comparison of the Flavored and Unflavored Omeprazole Delayed Release Tablets, 20 mg

Name of Constituent	Quantity per Tablet [mg]		Function of constituent	Grade			
	Unflavored	Flavored					
(b) (4)							
Omeprazole	20	20	Drug substance	USP			
Lactose Monohydrate	(b) (4)	(b) (4)	(b) (4)	NF			
Sodium Starch Glycolate				NF			
Sodium Stearate				NF			
Sodium Stearyl Fumarate				NF			
(b) (4)							
Hypromellose Acetate Succinate				NF			
Talc				USP			
Triethyl Citrate				NF			
Monoethanolamine				NF			
Sodium Lauryl Sulfate				NF			
(b) (4)					(b) (4)		
Menthol				(b) (4)	(b) (4)	NF	(b) (4)
(b) (4)							
Sucralose							NF
Carnauba wax				NF			
Total weight	307	307					

(b) (4)

Pharmaceutical Development

Dexcel Pharma has used (b) (4) to develop a flavored product of Omeprazole Delayed Release Tablets, 20mg. The applicant intends to include the flavored formulation in the same NDA and it should be therapeutically equivalent to the current approved Omeprazole Delayed Release Tablets, 20mg.

Quality Target Product Profile

Based on the clinical and pharmacokinetic (PK) characteristics as well as the in vitro dissolution and physicochemical characteristics of the current approved formulation, a quality target product profile (QTPP) was defined for the additional flavored formulation (**Table 2**).

Table 2: Quality Target Product Profile (QTPP) for Flavored Product

QTPP Elements		Target	Justification
Dosage form		capsule shaped, film coated tablets	Pharmaceutical equivalence to the approved formulation
Dosage design		Delayed release tablet with debossment on one side, with different color and odor.	Same dosage design as RLD; Differs from RLD in color and odor in order to differentiate between the current formulation
Route of administration		Oral	Pharmaceutical equivalence requirement: same route of administration
Dosage strength		20mg	Same as the approved formulation
Pharmacokinetics		AUC and Cmax within the limit of 80 to 125 percent to the approved formulation.	Bioequivalent requirements
Stability		At least 24 month shelf life at RT	Equivalent to the approved formulation
Drug product quality attributes	Physical Attributes	Comply with the current specification, except for color	Pharmaceutical equivalence requirement: Must meet the same compendial or other applicable (quality) standards (i.e., identity, assay, purity, and quality) as in the approved product
	Identification		
	Assay		
	Uniformity of dosage unit		
	Dissolution		
	Degradation Products		
	Gastric resistant		
Moisture content			
Container closure system		Approved container closure system qualified as suitable for this drug product will be used	The additional formulation will be packed using same container closure system but with a different label

Table 3 summarizes the quality attributes of the flavored product and indicates which attributes were classified as drug product critical quality attributes (CQAs), especially with respect to the coating layer. Assay, dissolution, gastric resistance and degradation products were identified as the subset of CQAs that have the potential to be impacted by the coating formulation and/or its process variables and, therefore, these CQAs will be investigated and discussed in detail in subsequent formulation and process development studies.

Table 3: Critical Quality Attributes (CQAs) of Flavored Formulation

Quality Attributes of the Drug Product		Target	Is this a CQA?	Justification
Physical attribution	Appearance	Color and shape acceptable to the patient. No visual tablet defects observed.	No	Color, shape and appearance are not directly linked to safety and efficacy. Therefore, they are not critical. The target is set to ensure patient acceptability and to differentiate the flavor product from unflavored product
	Odor	Pleasant odor	No	In general, a noticeable odor is not directly linked to safety and efficacy, but odor can affect patient acceptability. For this product, neither the drug substance nor the excipients have an unpleasant odor. (b) (4)
	Size	Same to the current formulation	No	For comparable ease of swallowing as well as patient acceptance and compliance with treatment regimens, the target for dimensions is set similar to the RLD (Omeprazole DR, Tablets, 20mg).
	Taste	Pleasant taste	No	Taste is not linked to safety and efficacy, but taste can affect patient acceptability. (b) (4)
	Debossment	Same as current formulation	No	Omeprazole DR, 20mg is with debossment "20" tablet: therefore, the flavor product will be same. (b) (4)
Identification				
Assay				
Uniformity of dosage unit				
Degradation Products				

Dissolution	(b) (4)
Gastric resistance	(b) (4)
	(b) (4)
	(b) (4)

applicant has not discussed in detail in the pharmaceutical development report. However, these CQAs are still target elements of the QTPP and are ensured through a good pharmaceutical quality system and are tested in the final product.

Initial Risk Assessment of the Formulation Variables

The aim of the formulation development was to achieve the targeted flavored product with the same dissolution profile as the reference product.

Risk assessment of the drug product formulation components was performed to the changed components: The new coloring mixture and new flavoring ingredients.

Changes in components or composition that have the effect of adding a new excipient or deleting an excipient are defined as level 3 (Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms). However, specifically, changes of an ingredient affecting the color or flavor are viewed as minor changes resulting in product formulation that are considered to be the same from the aspects of bioavailability [Guidance for Industry Submission of Summary Bioequivalence Data for ANDAs, May 2011, 21 CFR 320.22(d)(4)]. The initial risk assessment is presented in **Table 4**.

Table 4: Justification for the Initial Risk Assessment of the Formulation Variables

Formulation variables	Drug Product CQAs	Justification
New Coloring mixture	Degradation Products	(b) (4)
	Assay	
	Dissolution	
	Gastric resistance	
Flavoring ingredients	Degradation Products	
	Assay	
	Dissolution	
	Gastric resistance	

Formulation Development Studies

(b) (4)



Conclusion



(b) (4)

(b) (4)

This formulation was chosen for the bioequivalence study and as the final flavored formulation.

DRUG SUBSTANCE



(b) (4)

DRUG PRODUCT

(b) (4)

(b) (4) was used to develop a flavored product of Omeprazole Delayed Release Tablets, 20mg.

Bioequivalence study was performed for the flavored formulation versus the reference product, Omeprazole Delayed Released Tablets, 20 mg and according to the applicant the two formulations are bioequivalent.

Composition of the Drug Product

Unit Composition

Table 5: Flavored, Purple Colored Omeprazole Delayed Release Tablets, 20 mg

Name of Constituent	Quantity per Tablet [mg]	Function of constituent	Quality standard
Omeprazole	20.0	Drug substance	USP
Lactose Monohydrate	(b) (4)	(b) (4)	NF
Sodium Starch Glycolate			NF
Sodium Stearate			NF
Sodium Stearyl Fumarate			NF
(b) (4)			
Hypromellose Acetate Succinate			NF
Talc			USP
Triethyl Citrate			NF
Monoethanolamine			NF
Sodium Lauryl Sulfate			NF
(b) (4)			(b) (4)
(b) (4)			(b) (4)
Menthol			NF
(b) (4)			(b) (4)
Sucralose			NF
Carnauba wax	NF		
Total weight	307	(b) (4)	

(b) (4)

Inactive Ingredients and Amounts are Appropriate per Inactive Ingredient Database (IID)

The maximum recommended daily dose for Omeprazole Delayed Released Tablets, 20mg is 20 mg. As shown in the table below, all inactive ingredients used in the manufacture of the flavored Omeprazole Delayed Released Tablets, 20mg are within the allowable amount in FDA's **Inactive Ingredients Database (IID)**, (b) (4)

Table 8: Inactive Ingredients and Amounts per IID

Name of Constituent	Max. Daily dose (mg)	IID Levels for Oral Products (mg)
Lactose Monohydrate	(b) (4)	587.44
Sodium Starch Glycolate	(b) (4)	876
Sodium Stearate	(b) (4)	10
Sodium Stearyl Fumarate	(b) (4)	29.3
Hypromellose Acetate Succinate	(b) (4)	560
Talc	(b) (4)	220.4
Triethyl Citrate	(b) (4)	20.177
Monoethanolamine	(b) (4)	1
Sodium Lauryl Sulfate	(b) (4)	51.69
(b) (4)	(b) (4)	0.05
Menthol	(b) (4)	14
(b) (4)	(b) (4)	----
Sucralose	(b) (4)	0.275
Carnauba wax	(b) (4)	300

Table 11: Batch Formula

Name of Constituent:	Standard
(b) (4)	
Omeprazole	USP
Lactose Monohydrate	NF
Sodium Starch Glycolate	NF
Sodium Stearate	NF
Sodium Stearyl Fumarate	NF
(b) (4)	
Hyppromellose Acetate Succinate	NF
Talc	USP
Triethyl Citrate	NF
(b) (4)	
Monoethanolamine	NF
Sodium Lauryl Sulfate	NF
(b) (4)	
Sucralose	NF
Flavor	In-House standard
Menthol	NF
(b) (4)	
Carnauba Wax	NF

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Biopharm Consult: Biopharm consult request was submitted on, 4/2/2014.

Comment: The Biopharm review by Tien Mien Chen, Ph.D., dated 7/18/2014, has recommended Complete Response (CR) for this PAS-024. The following Biopharmaceutics comment needs to be conveyed to the applicant in the CR letter:

- Only one set of dissolution profile data of three pivotal batch Nos. B.N. BY150813, 160813, and 170813 was provided, which were all coated with the same flavor, (b) (4). Clarify if this batch data is for the (b) (4). In order to support the approval of this PAS-024, provide to the Agency for review another set of comparative dissolution profile data to support the (b) (4) flavor.

Expiration Dating

The same expiration date will be assigned to the flavored tablets packaged in blisters and in bottles. Therefore, a shelf-life of 24 months is proposed for the flavored Omeprazole Delayed Release Tablets, 20mg in the two container closure systems.

Comment: Based on stability data, the proposed 24-month stability data is acceptable.

Post -Approval Commitment

(b) (4)

Conclusion:

Based on stability data presented in this submission the proposed flavored Omeprazole Delayed Release Tablets, 20 mg and the current unflavored Omeprazole Delayed Release Tablets, 20 mg are considered as equivalent.

LABELING:

(b) (4)

Information Request

The following deficiencies should be communicated to the applicant:

- Section 3.2.P.2 states that (b) (4) was used to develop the flavored product, Omeprazole Delayed Release Tablets, 20 mgt. Clarify what is the proposed design space or the (b) (4) elements in this change.
- Only one flavor (b) (4) formulation is included in the submission. Provide formulation for the (b) (4) flavor. In addition, clarify if the formulation in the submission is for (b) (4)
- Provide stability data for the (b) (4) flavor under long term, intermediate and accelerated conditions.
- Only one set of dissolution profile data of three pivotal batch Nos. B.N. BY150813, 160813, and 170813 was provided, which were all coated with the same flavor, (b) (4). Clarify if this batch data is for the (b) (4). In order to support the approval of this PAS-024, provide to the Agency for review another set of comparative dissolution profile data to support the (b) (4) flavor.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KRISHNA P RAMAN
07/21/2014
Issue CR action letter.

RAMESH RAGHAVACHARI
07/24/2014
Complete Response

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

BIOPHARMACEUTICAL REVIEW(S)

ONDQA BIOPHARMACEUTICS REVIEW

NDA#:	22032/S-024
Submission Date:	03/15/14
Generic Name:	Omeprazole
Formulation:	DR (delayed release) oral tablet
Strength:	20 mg for OTC (over-the-counter) use
Applicant:	Dexcel Pharma
Type of submission:	PAS (Prior approval supplement)
Reviewer:	Tien-Mien Chen, Ph.D.

SYNOPSIS

Background

Dexcel Pharma's NDA 22032 for Omeprazole DR 20 mg tablets for OTC (over-the-counter) use was approved on 12/04/07. It is indicated for treating frequent heartburn (occurs 2 or more days a week), but not intended for immediate relief of heartburn. It may take 1 to 4 days for full effect.

Current Submission

On 03/15/14, Lachman Consultant Services, Inc. on behalf of Dexcel Pharma submitted a PAS-024 seeking approval for the flavored Omeprazole DR 20 mg tablets.

Dexcel Pharma reported that

- There will be (b) (4) flavors proposed, (b) (4)
- Dexcel intends to market both the flavored and unflavored (i.e., currently approved on the market) Omeprazole DR 20 mg tablets.
- The formulation of the flavored Omeprazole DR 20 mg tablets is quantitatively and qualitatively the same as the current formulation, except for a replacement of the color mixture and the addition of a berry flavor, sucralose and menthol. The flavor is to generate a sensation of a berry flavor and cooling effect.
- The tablet shape of flavored tablets is the same as the approved (unflavored) product, but is different in color (purple instead of brownish) to ease the differentiation of the flavored product from the current product by patients.

- (b) (4)
-
-

-
-
-
-

The stability data submitted and the proposed manufacturing changes are reviewed by the chemist/ONDQA

A bioequivalence (BE) study and the comparative dissolution profile data between the flavored and unflavored Omeprazole DR 20 mg tablets were also submitted to support the proposed changes described in this PAS-024. The BE study No. 130356 is considered not needed to support the change to the flavor. Therefore, only the comparative dissolution profile data are reviewed by the Biopharmaceutics/ONDQA.

Biopharmaceutics Review

The Biopharmaceutics review is focused on the evaluation and acceptability of the comparative dissolution profile data.

Formulation/Composition:

The formulation/composition of the current unflavored and the proposed flavored Omeprazole DR 20 mg tablets for OTC use is shown below.

Table 1. Formulation/Composition of Current Unflavored and the Proposed Flavored Omeprazole DR 20 mg Tablets for OTC Use

Name of Constituent	Quantity per Tablet [mg]		Function of constituent	Grade		
	Unflavored	Flavored				
(b) (4)						
Omeprazole	20	20	Drug substance	USP		
Lactose Monohydrate	(b) (4)	(b) (4)		NF		
Sodium Starch Glycolate			NF			
Sodium Stearate			NF			
Sodium Stearyl Fumarate			NF			
(b) (4)						
Hypromellose Acetate Succinate			NF			
Talc			USP			
Triethyl Citrate			NF			
Monoethanolamine			NF			
Sodium Lauryl Sulfate			NF			
(b) (4)					(b) (4)	
(b) (4)						
Menthol			(b) (4)			NF
(b) (4)						(b) (4)
Sucralose				NF		
Carnauba wax				NF		
Total weight	307	307				
(b) (4)						

The above proposed changes to the film coat color and the addition of flavor are considered minor according to SUPAC guidance.

Comparative Dissolution Profile Data:

The FDA currently approved dissolution method as shown below was employed for comparative dissolution testing.

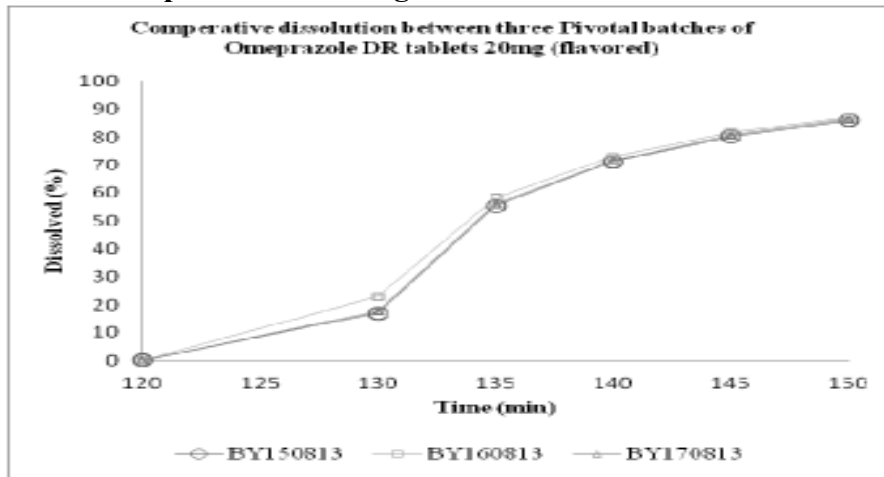
Apparatus: USP II (Paddle) with 100 rpm
Medium: Acid Stage: 0.1 N HCl 750 mL for 2 hrs
Buffer Stage: pH 6.8 phosphate buffer, 1000mL at 37°C
Acceptance
Criterion: Q= (b) (4) at 30 min

1. Comparative dissolution profile data of the three flavored batch Nos. BY150813, BY160813, BY170813 are shown below.

Table 2. Mean Comparative Dissolution Data (n=12 tablets/batch)

Time (min)	Dissolution (%) Omeprazole DR Tablets 20mg (flavored) Pivotal Batches		
	BY150813	BY160813	BY170813
0	0	0	0
120	0	0	0
130	17.0	23.0	17.8
135	55.4	58.3	56.0
140	71.3	73.1	71.7
145	80.3	81.7	80.8
150	86.0	87.2	86.5

Figure 1. Comparative Dissolution Profile of Three Stability Batches of Flavored Omeprazole DR 20 mg Tablets

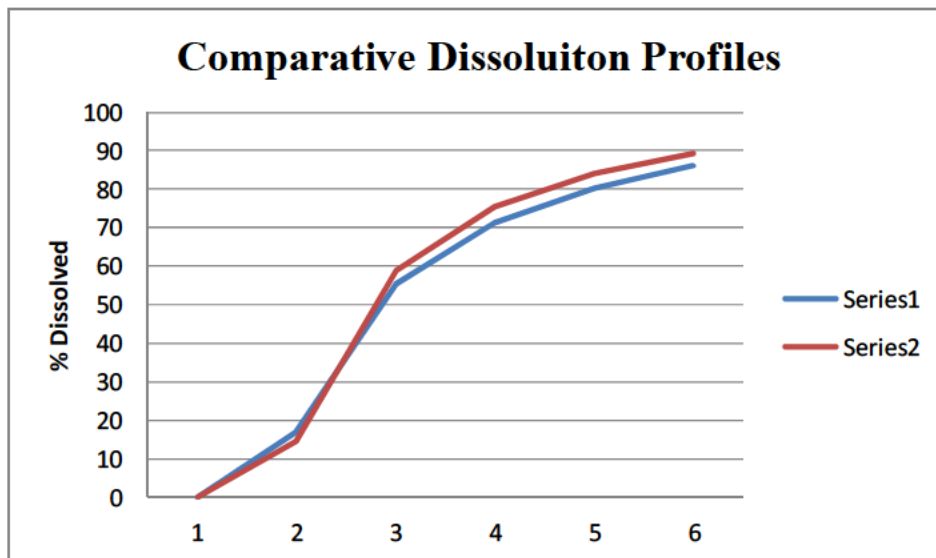


2. Comparative Dissolution Profiles of the Biobatch Nos. BY150813 (Flavored; Test) and BY701109 (Current, unflavored; Reference) Omeprazole DR 20 mg Tablets used in the BE study No. 130356.

Table 3. Mean Comparative Dissolution Data (n=12 tablets/batch)

Time (Min)	Comparative Dissolution (%) of Omeprazole DR 20 mg Tablet Biobatches Used in BE study No. 130356	
	No. BY150813	No. BY701109
0	0	0
120	0	0
130	17.0	14.6
135	55.4	58.8
140	71.3	75.3
145	80.3	84.2
150	86.0	89.3

Figure 2. Mean Comparative Dissolution Profile of the Biobatch Nos. BY150813 (Flavored; Test; Blue curve) and BY701109 (Current, unflavored; Reference; Red Curve) Omeprazole DR 20 mg Tablets



Note: Blue curve is for Test and Red curve is for Ref products and Time (X-axis) is in a 5-min increment.

The similarity factor (f2) was calculated to be 74.1 indicating similarity between the two dissolution profiles.

Reviewer's Comments:

The proposed changes of adding flavor to the currently approved unflavored Omeprazole DR 20 mg tablets is reviewed. The dissolution data presented in this submission demonstrate that based on the similarity factor (f2) calculated, 74.1, the proposed flavored Omeprazole DR 20 mg tablets and the current unflavored Omeprazole DR 20 mg tablets are similar. This PAS-024, however, supports the addition of only one of the (b) (4) flavors proposed to the Omeprazole DR 20 mg tablets, (b) (4)

Finally, the BE study No. 130356 conducted is not reviewed for it is considered not needed to support the minor changes to the flavor.

RECOMMENDATION

From the Biopharmaceutics perspective, it is recommended CR (complete response) for this PAS-024. The following Biopharmaceutics comment needs to be conveyed to the Applicant in the CR letter.

COMMENT: (Needs to be sent to the Applicant)

- Only one set of dissolution profile data of three pivotal batch Nos. B.N. BY150813, 160813, and 170813 was provided, which were all coated with the same flavor, (b) (4). Clarify if this batch data is for the (b) (4) flavor. In order to support the approval of this PAS-024, provide to the Agency for review another set of comparative dissolution profile data to support the (b) (4) flavor.

Tien-Mien Chen, Ph.D.
ONDQA Biopharmaceutics Reviewer

07/18/14

Date

Tapash Ghosh, Ph.D.
ONDQA Biopharmaceutics Team Leader

07/18/14

Date

CC: DARRTS/NDA No.22032/PAS-024\RLostritto

**sNDA 22032/S-024 for OTC Omeprazole
DR 20 mg Tablets**

Appendix

**Mean and Individual Dissolution Data
(n=12 tab/batch)**

I. Three Flavored Batch Nos. BY150813, BY160813, BY170813 of Proposed OTC Omeprazole DR 20 mg tablets

Batch-to-batch variability

Dissolution data for 3 production batches of flavored Omeprazole Delayed Released tablets, 20 mg tested using the approved dissolution method revealed the following results:

Time (min)	Dissolution (%)													Average	RSD Individual
	B.N BY150813- Test batch in BE 130356														
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12			
0	(b) (4)												0	NA	
120	(b) (4)												0	NA	
130	(b) (4)												17.0	60.0	
135	(b) (4)												55.4	10.2	
140	(b) (4)												71.3	4.7	
145	(b) (4)												80.3	2.9	
150	(b) (4)												86.0	2.0	

Time (min)	Dissolution (%)													Average	RSD Individual
	B.N BY160813														
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12			
0	(b) (4)												0	NA	
120	(b) (4)												0	NA	
130	(b) (4)												23.0	39.8	
135	(b) (4)												58.3	6.0	
140	(b) (4)												73.1	2.9	
145	(b) (4)												81.7	2.1	
150	(b) (4)												87.2	1.9	

Time (min)	Dissolution (%)													Average	RSD Individual
	B.N BY170813														
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12			
0	(b) (4)												0.0	NA	
120	(b) (4)												0.0	NA	
130	(b) (4)												17.8	59.1	
135	(b) (4)												56.0	7.3	
140	(b) (4)												71.7	4.0	
145	(b) (4)												80.8	3.1	
150	(b) (4)												86.5	2.9	

All batches comply with the specification of N.L.T ^{(b) (4)}(Q). As seen per 12 individual tablets, average results, the three pivotal batches revealed similar dissolution profile.

II. The Biobatch Nos. BY150813 (flavored) and BY701109 (Current OTC) Omeprazole DR 20 mg tablets

Comparative Dissolution Profile

BY150813-Flavored Omeprazole DR (Tested batch)

vs.

Y1308149-Omeprazole DR (Reference batch) BE 130356

Dissolution Data for 12 individual tablets for the test batch (BY150813) and the reference batch (Y1308149) used in the current bioequivalence study is shown below.

Time (min)	Dissolution (%)												Average	RSD Individual
	B.N BY150813 (flavored) –Test batch in BE 130356													
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12		
0	(b) (4)												0	NA
120	(b) (4)												0	NA
135	(b) (4)												55.4	10.2
140	(b) (4)												71.3	4.7
145	(b) (4)												80.3	2.9
150	(b) (4)												86.0	2.0

Time (min)	Dissolution (%)												Average	RSD Individual
	B.N Y1308149 –Reference batch in BE 130356													
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12		
0	(b) (4)												0	NA
120	(b) (4)												0	NA
135	(b) (4)												42.8	0.13
140	(b) (4)												66.9	0.04
145	(b) (4)												78.7	0.02
150	(b) (4)												85.4	0.01

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/s/

TIEN MIEN CHEN
07/18/2014

TAPASH K GHOSH
07/18/2014

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s024

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

From: [Buchanan, Jeffrey A.](#)
To: m.desposito@lachmanconsultants.com
Cc: [Buchanan, Jeffrey A.](#)
Subject: NDA 22032 S-024 omeprazole - Information Request
Date: Wednesday, January 28, 2015 1:30:37 PM
Attachments: [42-ct 3-pack blister.pdf](#)
[42-ct value pack blister.pdf](#)
Importance: High

Hi Mary-Anne,

We have the following Information Request pertaining to the above-referenced application:

- *The Drug Facts labels for the 42-ct blister carton with the red “3 PACK Three 14-day courses of treatment” flag and the 42-ct blister carton with the yellow “Value Pack! 3-14 Tablet Cartons” flag are illegible and cover less than half of the back of the carton. Submit revised labeling with appropriate Drug Facts labeling no later than Monday, February 2, 2015, in order to meet the PDUFA date for this supplement.*

You may reference the attached labels. Please feel free to contact me should you have questions.

Jeffrey Buchanan

U.S. Food and Drug Administration
FDA/OMPT/CDER/OND/ODE IV/DNDP
White Oak Building 22, Room 5461
10903 New Hampshire Avenue
Silver Spring, Maryland

Use zip code **20903** if shipping via United States Postal Service (USPS).

(b) (4)

Phone: (301) 796-1007 Fax: (301) 796-9899

Email: jeffrey.buchanan@fda.hhs.gov

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/s/

JEFFREY A BUCHANAN
01/28/2015



NDA 022032/S-024

COMPLETE RESPONSE – CMC

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S.
Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated March 15, 2014, received March 18, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

We also refer to your October 15, 2014 resubmission, received October 15, 2014, to your supplemental new drug application.

This resubmission constitutes a complete response to our September 29, 2014 action letter. The user fee goal date is February 13, 2015.

If you have questions, contact me at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Jeffrey Buchanan
Regulatory Health Project Manager
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

JEFFREY A BUCHANAN
12/03/2014

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Lachman Consultants acknowledged receipt of the email below via telephone call on 12/01/14 @1640hrs. They advised their emails to FDA are being returned as undeliverable and they are communicating with FDA via *telephone only* at this time. Their IT Admin is investigating the issue.

Jeff Buchanan

From: [Buchanan, Jeffrey A.](#)
To: m.desposito@lachmanconsultants.com
Cc: [Buchanan, Jeffrey A.](#)
Subject: NDA 22032 S-024 omeprazole - Information Request
Date: Monday, December 01, 2014 4:05:15 PM
Importance: High

Hi Mary-Anne,

We have the following Information Request relative to your Resubmission/After-Action Complete Response for NDA 22032 S-024 omeprazole. Please respond by close of business December 15, 2014. Feel free to contact me, should you have questions.

- The name of the coating (b) (4) is misleading. Data from the sensory evaluation submitted on July 18, 2014, describes the flavor of the placebo tablet as both berry and mint, with an aftertaste that was more strongly mint than berry. Please correct the name of the flavor to accurately reflect the study data.

Jeffrey Buchanan

U.S. Food and Drug Administration
FDA/OMPT/CDER/OND/ODE IV/DNDP
White Oak Building 22, Room 5461
10903 New Hampshire Avenue
Silver Spring, Maryland

*Use zip code **20903** if shipping via United States Postal Service (USPS).*

(b) (4)

Phone: (301) 796-1007 Fax: (301) 796-9899

Email: jeffrey.buchanan@fda.hhs.gov

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/s/

JEFFREY A BUCHANAN
12/01/2014



NDA 022032/S-024

**REVIEW EXTENSION –
CMC SUPPLEMENT**

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S., Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated March 13, 2014, received March 18, 2014, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for omeprazole delayed-release tablets, 20 mg.

On July 18, 2014, we received your July 18, 2014 major amendment to this application. Therefore, we are extending the goal date by two months to provide time for a full review of the submission. The extended user fee goal date is September 18, 2014.

If you have questions, call Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

THERESA M MICHELE
07/18/2014

McKnight, Rebecca

From: McKnight, Rebecca
Sent: Friday, April 25, 2014 12:27 PM
To: m.desposito@lachmanconsultants.com
Subject: IR Questions for NDA 22032/S-024

Dear Ms. D'Esposito,

We are reviewing NDA 22032/S-024, and would request the following information:

1. Data that demonstrates that consumers experience a flavor coating containing menthol as (b) (4) flavor.
2. Label Comprehension study data for the proposed label that demonstrates consumer understanding that the flavored tablets are to be swallowed whole and not chewed.
3. Data to support a treatment effect claim of heartburn relief such as (b) (4). Refer the sponsor to *Guidance for Industry – Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims*.

If you have any questions, please contact me.

Thank you,

Rebecca McKnight
Regulatory Health Project Manager
Division of New Drug Quality Assessment III
CDER – ONDQA
Food and Drug Administration
(301) 796-1765

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/s/

REBECCA A MCKNIGHT
04/25/2014



NDA 22032/S-024

**ACKNOWLEDGEMENT --
PRIOR APPROVAL SUPPLEMENT**

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S., Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 22032
SUPPLEMENT NUMBER: S-024
PRODUCT NAME: Omeprazole Delayed Release Tablets
DATE OF SUBMISSION: March 13, 2014
DATE OF RECEIPT: March 18, 2014

This supplemental application proposes the following change(s): the addition of flavored Omeprazole Delayed Release Tablets, 20 mg.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on May 17, 2014, in accordance with 21 CFR 314.101(a).

If the application is filed, the user fee goal date will be July 18, 2014.

SUBMISSION REQUIREMENTS

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Non-Prescription Clinical Evaluation
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>.

If you have questions, call me, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Rebecca McKnight
Regulatory Health Project Manager
Division of New Drug Quality Assessment III
Office of New Drug Evaluation
Center for Drug Evaluation and Research

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/s/

REBECCA A MCKNIGHT
04/17/2014

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022032Orig1s052

Trade Name: Omeprazole

Generic or Proper Name: Omeprazole

Sponsor: Dexcel Pharma Technologies Ltd.

Approval Date: October 1, 2021

Indication: Treats frequent heartburn (occurs 2 or more days a week)

CENTER FOR DRUG EVALUATION AND RESEARCH

022032Orig1s052

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
Labeling Review(s)	X
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Clinical Review(s)	
Chemistry Review(s)	X
Non-Clinical Review(s)	
Biopharmaceutical Review(s)	X
Clinical Microbiology / Virology Review(s)	
Pharmacology / Toxicology Review(s)	X
Other Reviews	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

APPROVAL LETTER

NDA 022032/S-052

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
c/o: Icon Clinical Research LLC (Authorized Agent)
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Drive
4401 Research Commons Bldg., Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received June 2, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed release tablets, 20 mg.

This “Prior Approval” supplemental new drug application provides for the addition of a cool mint flavored formulation and associated labeling.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Cool Mint Flavored Tablets Label Submitted on August 12, 2021:

1. 2-count immediate container label

Cool Mint Flavored Tablets Labeling Submitted on July 26, 2021:

2. 14-count immediate container (blister)
3. 14-count immediate container (bottle)
4. 14-count inner carton
5. 2-count physician sample outer carton (blister)
6. 14-count outer carton (blister)
7. 14-count outer carton with the “FDA Approved” statement (blister)

8. 14-count outer carton (bottle)
9. 14-count outer carton with the "FDA Approved" statement (bottle)
10. 28-count outer carton (blister)
11. 28-count outer carton with the "14 Free" statement (blister)
12. 28-count outer carton with the "Bonus! 14 Free" statement (blister)
13. 28-count outer carton with the "Bonus Pack! 14 Free" statement (blister)
14. 28-count outer carton with the "FDA Approved" statement (blister)
15. 28-count outer carton (bottle)
16. 28-count outer carton with the "14 Free" statement (bottle)
17. 28-count outer carton with the "Bonus! 14 Free" statement (bottle)
18. 28-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)
19. 28-count outer carton with the "FDA Approved" statement (bottle)
20. 42-count outer carton (blister)
21. 42-count outer carton with the "14 Free" statement (blister)
22. 42-count outer carton with the "Bonus! 14 Free" statement (blister)
23. 42-count outer carton with the "Bonus Pack! 14 Free" statement (blister)
24. 42-count outer carton with the "FDA Approved" statement (blister)
25. 42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (blister)
26. 42-count outer carton with the "28 + 14 FREE" statement (blister)
27. 42-count outer carton with the "Value Pack! Three- 14 Tablet Cartons" statement (blister)
28. 42-count outer carton with the "Triple Pack Three 14-day courses of treatment" statement (blister)
29. 42-count outer carton (bottle)
30. 42-count outer carton with the "14 Free" statement (bottle)
31. 42-count outer carton with the "Bonus! 14 Free" statement (bottle)
32. 42-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)
33. 42-count outer carton with the "FDA Approved" statement (bottle)
34. 42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (bottle)
35. 42-count outer carton with the "28 + 14 FREE" statement (bottle)
36. 42-count outer carton with the "Value Pack! Three- 14 Tablet Bottles" statement (bottle)
37. 42-count outer carton with the "Triple Pack Three 14-day courses of treatment" statement (bottle)
38. 14-count IRC (blister)
39. 14-count IRC (bottle)
40. 28-count IRC (blister)
41. 28-count IRC (bottle)
42. 42-count IRC (blister)
43. 42-count IRC (bottle)

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.¹ For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022032/S-052.**” Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future, (e.g., immediate containers containing more than 14-count, package sizes more than 42-count), a prior approval labeling supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.² Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names and PDUFA Reauthorization Performance Goals and Procedures – Fiscal Years 2018 Through 2022.*)

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, call Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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/s/

NUSHIN F TODD
10/01/2021 07:24:44 AM

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

LABELING

Swallow whole.
Do not chew, crush, or suck tablets.
First two doses of a 14-day course of treatment.
Do not take for more than 14 days
or more often than every 4 months
unless directed by a doctor.

47K1B 00 X1 071921

Coated with cool mint flavor

Omeprazole DR
Tablets 20mg

Acid reducer

Push tablet through foil.

Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor

Omeprazole DR
Tablets 20mg

Acid reducer

Push tablet through foil.

Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

***Location for
lot number and
expiration date***

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole D Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole D Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Swallow whole.
Do not chew, crush, or suck tablets.
One 14-day course of treatment
Do not take for more than 14 days
or more often than every 4 months
unless directed by a doctor.
47K00 00 X1 041621

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole D Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

Coated with cool mint flavor
Omeprazole DR Tablets 20mg
Acid reducer
Push tablet through foil.
Dexcel Pharma Technologies Ltd
10 Hakidma Street,
Yokneam 2069200, Israel

→ Location for
lot number and
expiration date



= No Print Area

Questions? 1-800-719-0289

NOT FOR RESALE

Trade FREQUENT Heartburn! **24HR**

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer
SWALLOW - DO NOT CHEW

14 TABLETS COOL MINT Coated Tablet

One 14-day course of treatment
May take 1 to 4 days for full effect



SAFETY FEATURE - Do not use if protected seal under cap is broken or missing. This label does not contain full product information. See caution for complete information. Read warnings and directions on carton before use. Retain carton for reference.

Drug Facts

Active Ingredient (in each tablet)	Purpose
Omeprazole 20 mg.....Acid reducer	
Use: ■ treats frequent heartburn (occurs 2 or more days a week), ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.	
Other Information	
■ read the directions and warnings before use ■ keep the carton, ■ contains important information, ■ store at 20-25°C (68-77°F) and protect from moisture	

Manufactured by:
Teva Pharmaceuticals Ltd
10 Hulsbosch Street, Wellesboro, New York 14895, USA

Made in Israel

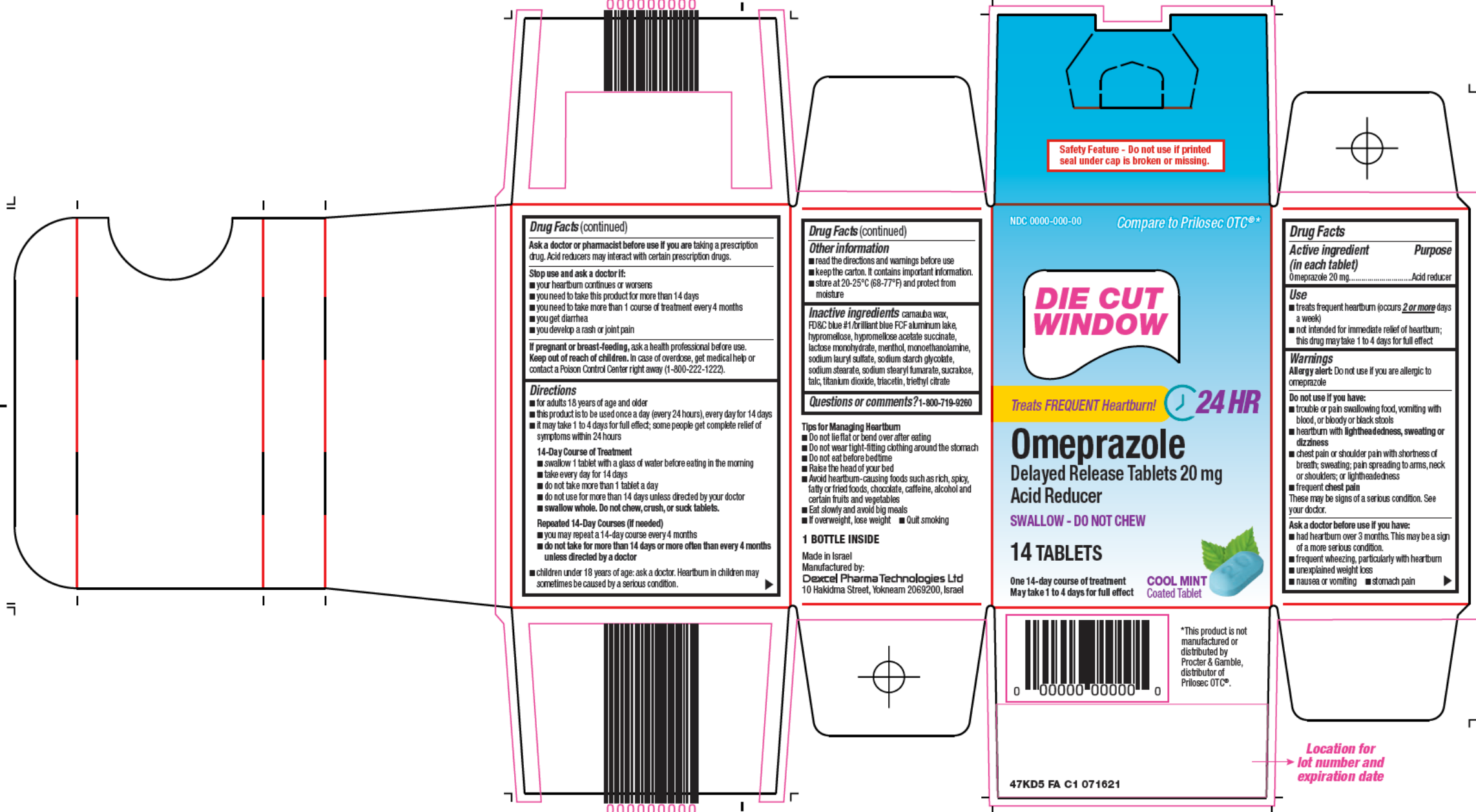
07-4624

: 47KD5 FA F1

Location for lot number and expiration date

FORMAT: NON-DFL	
TYPE SIZES:	
TITLE	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
HEADINGS	7 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	5 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Reference ID: 4866054



Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients camauba wax, FD&C blue #1/bright blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

1 BOTTLE INSIDE

Made in Israel
 Manufactured by:
Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel

NDC 0000-000-00 Compare to Prilosec OTC®*

DIE CUT WINDOW

Treats FREQUENT Heartburn! **24 HR**

Omeprazole
 Delayed Release Tablets 20 mg
 Acid Reducer

SWALLOW - DO NOT CHEW

14 TABLETS

One 14-day course of treatment
 May take 1 to 4 days for full effect

COOL MINT
 Coated Tablet

Drug Facts

Active ingredient (in each tablet)	Purpose
Omeprazole 20 mg	Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

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*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

47KD5 FA C1 071621

Location for lot number and expiration date

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients: camauba wax, FD&C blue #1, brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

1 BOTTLE INSIDE

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

NDC 0000 000-00 Compare to Prilosec OTC®+
FDA Approved

DIE CUT WINDOW

Treats FREQUENT Heartburn! **24 HR**

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

14 TABLETS

One 14-day course of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

Drug Facts

Active ingredient (in each tablet)	Purpose
Omeprazole 20 mg	Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

0 00000 00000 0

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

47KD5 FA C1-F 071021

Location for lot number and expiration date

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TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, nuts and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Drug Facts (continued)

Active ingredient (in each tablet) Omeprazole 20 mg, *Zorimax* acid reducer

Purpose Acid reducer

Use Treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings Do not use if you are allergic to omeprazole

Do not use if you have: trouble or pain swallowing, food, vomiting with blood, or bloody or black stools

Heartburn with lightheadedness, sweating or dizziness, chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness

These may be signs of a serious condition. See your doctor

Ask your doctor if you have: had heartburn over 3 months. This may be a sign of a more serious condition

Request hearing, particularly with heartburn

Unexplained weight loss

Nausea or vomiting

Stomach pain

Ask your doctor before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask doctor if: your heartburn continues or worsens

You need to take this product for more than 14 days

You need to take more than 1 course of treatment every 4 months

You get diarrhea

You develop a rash or joint pain

Drug Facts (continued)

Directions For adults 18 years of age and older: Take 1 to 4 days for full effect. This product is to be used once a day every 24 hours, every day for 14 days

It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment Swallow 1 tablet with a glass of water before eating in the morning

Take every day for 14 days

Do not take more than 1 tablet a day

Do not use for more than 14 days unless directed by your doctor

Swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed) You may repeat a 14-day course every 4 months

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor

Children under 18 years of age: Ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information Read the directions and warnings before use

Keep in original container. It contains important information.

Store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients camouba wax, FD&C blue #1, Avrilant blue, FCF aluminum lake, hypromellose acetate succinate, lactose monohydrate, mannitol, monobasic aluminum phosphate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

Location for lot number and expiration date

47K30 FA C1 071621

Safety Feature - Do not use if printed tablet blister unit is open or torn.



Omeprazole

Delayed Release Tablets 20 mg

NDC 0000-0000-00

Compare to Prilosec OTC[®]+

Treats FREQUENT Heartburn!



Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 TABLETS

Two 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



FORMAT: STANDARD

TYPE SIZES:

TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 and 6.6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 and 6.6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Tips for Managing Heartburn

- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Quit smoking
- Stop smoking
- Stop smoking

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg; ... Acid reducer

Purpose
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children in case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
For adults 18 years of age and older
For children 1 to 4 years of age
This product is to be used once a day, every 24 hours, every day for 14 days

Warnings
Do not use if you have:
trouble or pain swallowing food, vomiting with blood, or bloody or black stools
chest pain or shoulder pain in the shortness of breath, sweating, pain spreading to arms, neck or shoulders, or high blood pressure
recent chest pain
These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
had heartburn over 3 months. This may be a sign of a more serious condition.
frequent wheezing, particularly with heartburn
unexplained weight loss
nausea or vomiting
stomach pain

Ask a doctor before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
your heartburn continues or worsens
you need to take this product for more than 14 days
you need to take more than 1 course of treatment every 4 months
you get diarrhea
you develop a rash or joint pain

Other information
Read the directions and warnings before use
Keep the carton. It contains important information.
Store at 20-25°C (68-77°F) and protect from moisture.

Inactive ingredients
FCC aluminum lake, hypromellose acetate succinate, lactose monohydrate, mannitol, monobasic potassium phosphate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9280

Location for lot number and expiration date

47K30 FA C-1-E 071621

Safety Feature - Do not use if printed tablet blister unit is open or torn.



Omeprazole

Delayed Release Tablets 20 mg

Compare to Prilosec OTC**
Bonus! 14 Free

Treats FREQUENT Heartburn!



Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 ~~14~~ TABLETS

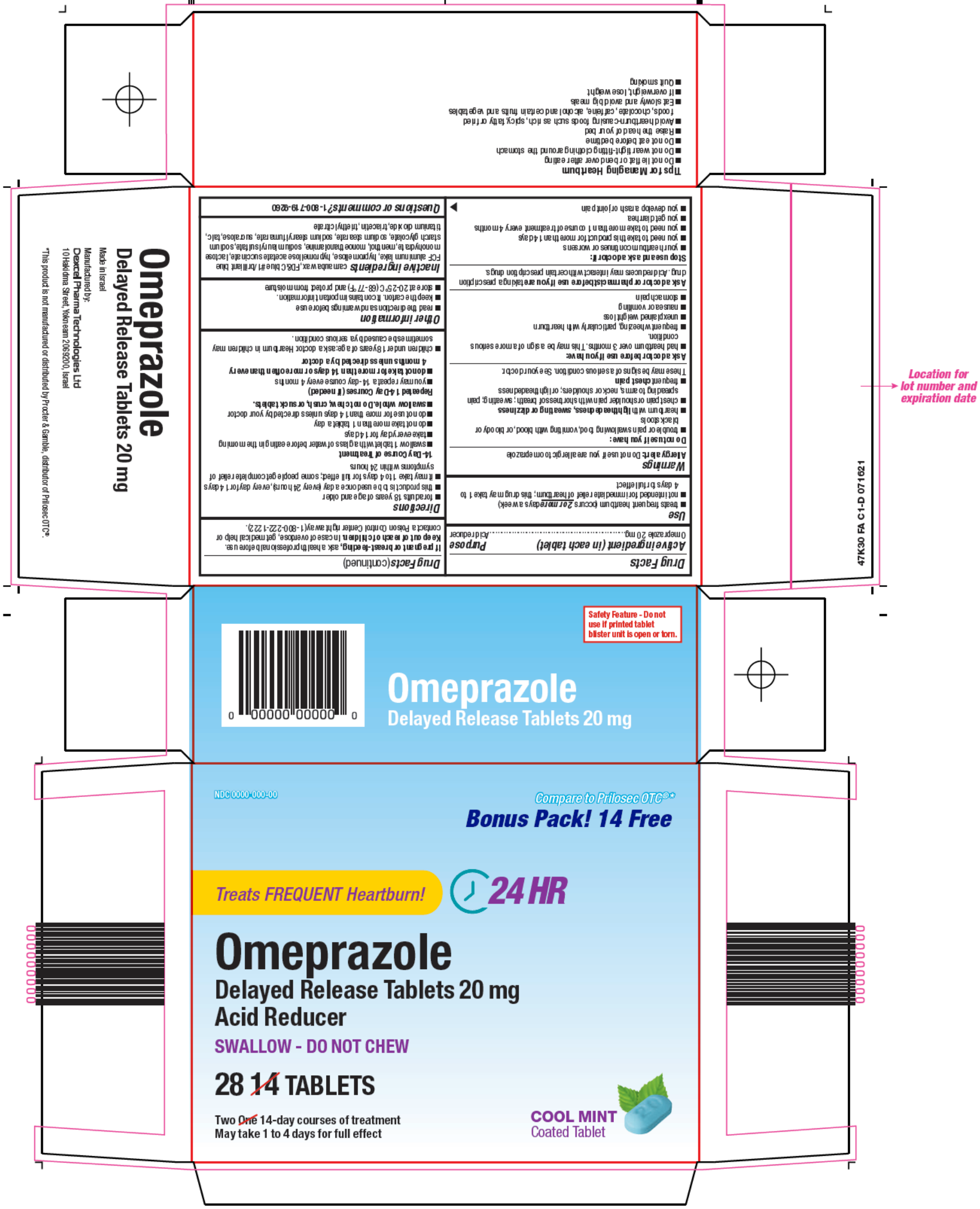
Two ~~One~~ 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



NDC 0000-0000-00

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 and 6.6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Location for lot number and expiration date

47K30 FA C-1-D 07 1621

Drug Facts (continued)

Active ingredient (in each tablet) Omeprazole 20 mg; Acid reducer

Purpose If you are taking a proton pump inhibitor (PPI) to treat heartburn, this drug may take 1 to 4 days to feel full effect.

Use Treats frequent heartburn (occurs 2 or more days a week). Not intended for immediate relief of heartburn; this drug may take 1 to 4 days to feel full effect.

Warnings Allergic reaction: Do not use if you are allergic to omeprazole. Do not use if you have: trouble or pain swallowing, blood, or body or black stools; heartburn with hives, dizziness, sweating, or dizziness; chest pain or trouble breathing; or pain in the chest, neck, or shoulder; or high blood pressure. These may be signs of a serious condition. See your doctor. frequent heartburn, particularly with heartburn; nausea or vomiting; stomach pain. Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if: your heartburn continues or worsens; you need to take this product for more than 14 days; you need to take more than 1 course of treatment every 4 months; you get diarrhea; you develop a rash or joint pain.

Other information Keep the carton, it contains important information. Read the directions and warnings before use. Store at 20-25°C (68-77°F) and protect from moisture. Inactive ingredients: calcium carbonate, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, magnesium stearate, sodium hydroxide, sodium starch glycolate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate.

Questions or comments? 1-800-719-9260

Drug Facts

Directions For adults 18 years of age and older: this product is to be used once a day, every day for 14 days. It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14-Day Course of Treatment Swallow 1 tablet with a glass of water before eating in the morning. Take every day for 14 days.

Repeat 14-Day Courses (if needed) Do not use for more than 14 days unless directed by your doctor. Swallow whole. Do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed) Do not use for more than 14 days unless directed by your doctor. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Other information Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

28 ~~14~~ TABLETS

Two ~~One~~ 14-day courses of treatment
May take 1 to 4 days for full effect

24 HR

Bonus Pack! 14 Free

Compare to Prilosec OTC**

COOL MINT
Coated Tablet

Safety Feature - Do not use if printed tablet blister unit is open or torn.

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 and 6.6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Drug Facts**Active ingredient (in each tablet) Purpose**
Omeprazole 20 mg.....Acid reducer**Use**

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings**Allergy alert:** Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens

Drug Facts (continued)

- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

- you get diarrhea ■ you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. ▶

Drug Facts (continued)**Other information**

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients carnauba wax, FD&C blue #1 brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triacetin, triethyl citrate**Questions or comments?** 1-800-719-9260**2 BOTTLES INSIDE**Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000-000-00

Compare to Prilosec OTC®*

DIE CUT WINDOW**DIE CUT WINDOW**Treats **FREQUENT Heartburn!****24 HR****Omeprazole**
Delayed Release Tablets 20 mg
Acid Reducer**SWALLOW - DO NOT CHEW****28 TABLETS**Two 14-day courses of treatment
May take 1 to 4 days for full effect**COOL MINT**
Coated Tablet**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

47KD6 FA C1 071621

Location for lot number and expiration date

FORMAT: STANDARD**TYPE SIZES:**

TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Safety Feature - Do not use if printed seal under cap is broken or missing.

Drug Facts

Active ingredient (in each tablet) Purpose
Omeprazole 20 mg.....Acid reducer

Use
■ treats frequent heartburn (occurs **2 or more** days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
■ your heartburn continues or worsens

Drug Facts (continued)

■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea ■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor

■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients camauaba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

2 BOTTLES INSIDE
Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

NDC 0000-000-00

Compare to Prilosec OTC®*

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

24 HR

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

28 TABLETS

Two 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



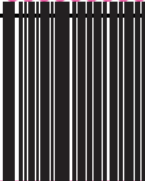
*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

47KD6 FA C1-B 071921

Location for lot number and expiration date

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(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Drug Facts (continued)**Other information**

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients carnauba wax, FD&C blue #1/bright blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

2 BOTTLES INSIDE

Made in Israel
Manufactured by:
Dexcal Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000 000-00

Compare to Prilosec OTC®*

Bonus! 14 Free**DIE CUT WINDOW****DIE CUT WINDOW**Treats **FREQUENT** Heartburn!**24 HR**

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW**28 14 TABLETS**

Two ~~one~~ 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



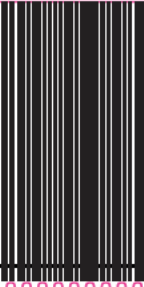
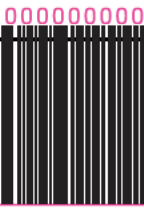
*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD6 FA C1-E 071921

FORMAT: STANDARD**TYPE SIZES:**

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SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Drug Facts

Active ingredient (in each tablet) Purpose
Omeprazole 20 mg.....Acid reducer

Use
■ treats frequent heartburn (occurs **2 or more** days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
■ your heartburn continues or worsens

Drug Facts (continued)

■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months

■ you get diarrhea ■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor

■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information

■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients carnauba wax, FD&C blue #1/bright blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

2 BOTTLES INSIDE
Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000-000-00

Compare to Prilosec OTC®*

Bonus Pack! 14 Free



Treats FREQUENT Heartburn!



Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

28 14 TABLETS

Two **14** 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD6 FA C1-D 071921

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TYPE SIZES:	
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SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Safety Feature - Do not use if printed seal under cap is broken or missing.

Drug Facts
Active ingredient (in each tablet) Purpose
 Omeprazole 20 mg.....Acid reducer

Use
 ■ treats frequent heartburn (occurs 2 or more days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
 ■ your heartburn continues or worsens

Drug Facts (continued)
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea ■ you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
 ■ for adults 18 years of age and older
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
 ■ swallow 1 tablet with a glass of water before eating in the morning
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor

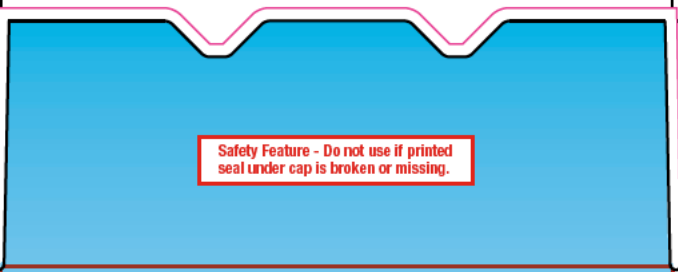
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. ▶

Drug Facts (continued)
Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients carnauba wax, FD&C blue #1, brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

2 BOTTLES INSIDE
 Made in Israel
 Manufactured by:
Oxcel Pharma Technologies Ltd
 10 Hakidma Street, Yokneam 2069200, Israel



NDC 0000-000-00

Compare to Prilosec OTC®*

FDA Approved

DIE CUT WINDOW **DIE CUT WINDOW**

Treats FREQUENT Heartburn!

24 HR

Omeprazole
 Delayed Release Tablets 20 mg
 Acid Reducer
 SWALLOW - DO NOT CHEW

28 TABLETS

Two 14-day courses of treatment
 May take 1 to 4 days for full effect

COOL MINT
 Coated Tablet

Tips for Managing Heartburn
 ■ Do not lie flat or bend over after eating
 ■ Do not wear tight-fitting clothing around the stomach
 ■ Do not eat before bedtime
 ■ Raise the head of your bed
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 ■ Eat slowly and avoid big meals
 ■ If overweight, lose weight
 ■ Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD6 FA C1-F 071921

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HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Location for lot number and expiration date

47K55 FA C1 071621

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer

Use
 ■ Treat frequent heartburn (occurs 2 or more days a week)
 ■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
 ■ Do not use if you have:
 ■ trouble or pain allowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or fainting, chest pain or shivering with shivers or fever
 ■ frequent chest pain
 ■ frequent stomach, neck or shoulder or high head edness
 ■ frequent chest pain
 ■ frequent chest pain
 ■ frequent chest pain
 ■ frequent chest pain

Do not use if you have:
 ■ trouble or pain allowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or fainting, chest pain or shivering with shivers or fever
 ■ frequent chest pain
 ■ frequent chest pain
 ■ frequent chest pain
 ■ frequent chest pain

Ask a doctor before use if you have:
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting
 ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea
 ■ you develop rash or joint pain

Other information

- Read the directions and warnings before use
- Keep the carton. It contains important information.
- Store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients
 FCF aluminum hydroxide, hydroxypropyl methylcellulose, lactose monohydrate, methylcellulose, polyethylene glycol, sodium starch glycolate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose

Questions or comments? 1-800-719-9260

Omeprazole
 Delayed Release Tablets 20 mg

Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdama Street, Yokneam 2069200, Israel

This product is not manufactured or distributed by P. Rodar & Gamble, distributor of Prilosec OTC.



Omeprazole
 Delayed Release Tablets 20 mg

Safety Feature - Do not use if printed tablet blister unit is open or torn.

NDC 0000-000-00

Compare to Prilosec OTC[®]

Treats FREQUENT Heartburn!



Omeprazole
 Delayed Release Tablets 20 mg
 Acid Reducer

SWALLOW - DO NOT CHEW

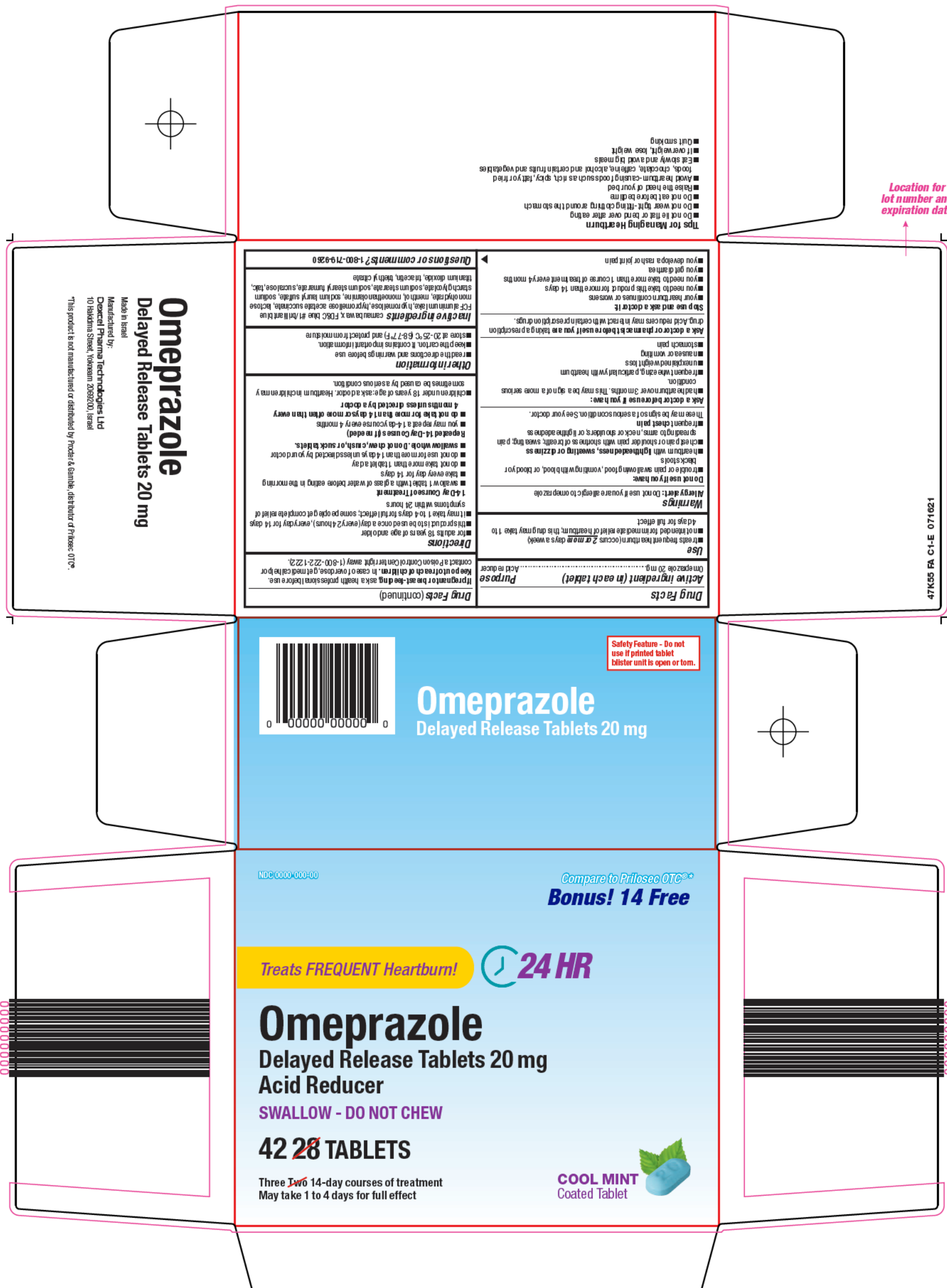
42 TABLETS

Three 14-day courses of treatment
 May take 1 to 4 days for full effect

COOL MINT
 Coated Tablet



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TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Location for lot number and expiration date

47K55 FA C1-E 071621



Omeprazole
Delayed Release Tablets 20 mg

Safety Feature - Do not use if printed tablet blister unit is open or torn.

NDC 0000-000-00

Compare to Prilosec OTC**
Bonus! 14 Free

Treats FREQUENT Heartburn! **24 HR**

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer
SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect



FORMAT: STANDARD	
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HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Location for lot number and expiration date

47K55 FA C1-D 071621

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Drug Facts

Active ingredient (in each tablet) Omeprazole 20 mg, Acid reducer

Use
 The active ingredient in heartburn (occurs 2 or more days a week) does not often need for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.

Warnings
 Allergy alert: Do not use if you are allergic to omeprazole.

Do not use if you have:
 Do not use if you have:
 chest pain or shoulder pain with arms or hands, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
 fainting or dizziness, sweating, or lightheadedness
 chest pain
 These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
 heartburn over 3 months. This may be a sign of a more serious condition.
 frequent wheezing, particularly with heartburn
 unexplained weight loss
 nausea or vomiting
 stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
 your heartburn continues or worsens
 you need to take this product for more than 14 days
 you get diarrhea
 you develop a rash or joint pain

Other information
 Keep the container closed until immediately before use.
 Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Questions or comments? 1-800-719-9260

Drug Facts (continued)

Directions
 For adults 18 years of age and older:
 Take 1 to 4 tablets once a day (every 24 hours), every day for 14 days.
 The product is to be used once a day (every 24 hours), every day for 14 days.
 Swallow 1 tablet with a glass of water before eating in the morning.
 Do not take more than 1 tablet a day.
 Do not use for more than 14 days unless directed by your doctor.
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 Do not take more than 1 tablet a day.
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Other information
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 Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Questions or comments? 1-800-719-9260

Active ingredient (in each tablet) Omeprazole 20 mg, Acid reducer

Use
 The active ingredient in heartburn (occurs 2 or more days a week) does not often need for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.

Warnings
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Do not use if you have:
 Do not use if you have:
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 fainting or dizziness, sweating, or lightheadedness
 chest pain
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Ask a doctor before use if you have:
 heartburn over 3 months. This may be a sign of a more serious condition.
 frequent wheezing, particularly with heartburn
 unexplained weight loss
 nausea or vomiting
 stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
 your heartburn continues or worsens
 you need to take this product for more than 14 days
 you get diarrhea
 you develop a rash or joint pain

Other information
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 Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Questions or comments? 1-800-719-9260

Drug Facts (continued)

Directions
 For adults 18 years of age and older:
 Take 1 to 4 tablets once a day (every 24 hours), every day for 14 days.
 The product is to be used once a day (every 24 hours), every day for 14 days.
 Swallow 1 tablet with a glass of water before eating in the morning.
 Do not take more than 1 tablet a day.
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 Do not take more than 1 tablet a day.

Other information
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 Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Questions or comments? 1-800-719-9260

Omeprazole
 Delayed Release Tablets 20 mg

Made in Israel
 Manufactured by:
 Cephalon Pharma Technologies Ltd
 10 Hahadima Street, Yokneam 2069200, Israel

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.

Omeprazole
 Delayed Release Tablets 20 mg

Safety Feature - Do not use if printed tablet blister unit is open or torn.

NDC 0000-000-00

Compare to Prilosec OTC[®]*
Bonus Pack! 14 Free

Treats **FREQUENT** Heartburn!

24 HR

Omeprazole
 Delayed Release Tablets 20 mg
 Acid Reducer

SWALLOW - DO NOT CHEW

42 ~~28~~ TABLETS

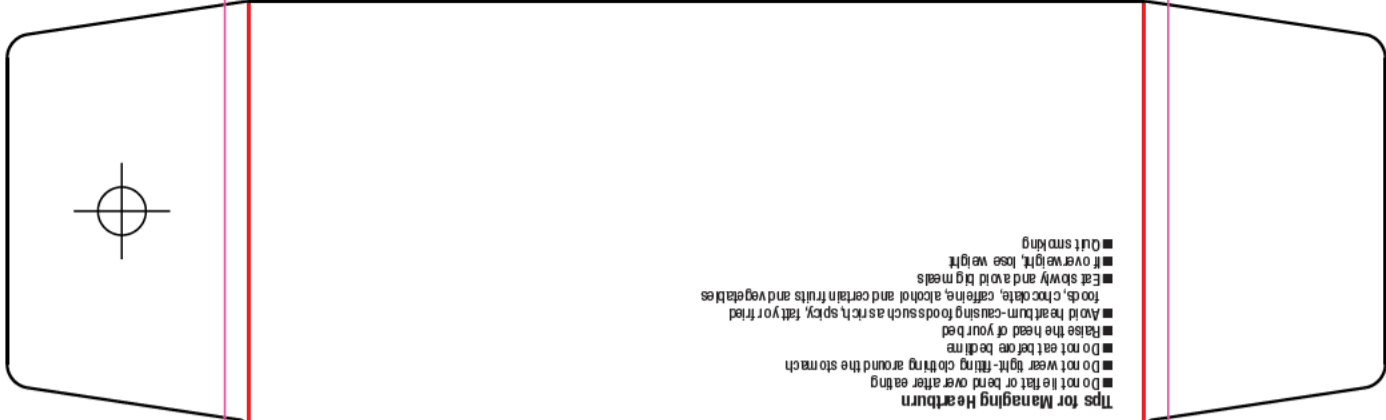
Three ~~Two~~ 14-day courses of treatment
 May take 1 to 4 days for full effect

COOL MINT
 Coated Tablet

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TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Location for lot number and expiration date

47K55 FA C1-F 071621



Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Drug Facts

Active ingredient (in each tablet) Omeprazole 20 mg

Purpose Acid reducer

Use Tablets require heartburn (occurs 2 or more days a week) not then ded to rim mediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- frequent chest pain
- trouble breathing

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- trouble swallowing or difficulty swallowing
- trouble breathing
- stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

Questions or comments? 1-800-719-2630

Other information

- Keep the carton. It contains important information.
- Store at 20°-25°C (68°-77°F) and protect from moisture.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- For adults 18 years of age and older: this product is to be used once a day (every 24 hours), every day for 14 days
- For children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

14-Day Course of Treatment

- swallow with a glass of water before eating in the morning
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take more than 1 day or more often than every 4 months unless directed by a doctor

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Drug Facts (continued)

Important information: Ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- For adults 18 years of age and older: this product is to be used once a day (every 24 hours), every day for 14 days
- For children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

14-Day Course of Treatment

- swallow with a glass of water before eating in the morning
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not chew, crush, or suck tablets.

Repeat 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take more than 1 day or more often than every 4 months unless directed by a doctor

Other information

- Keep the carton. It contains important information.
- Store at 20°-25°C (68°-77°F) and protect from moisture.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Questions or comments? 1-800-719-2630

Omeprazole
Delayed Release Tablets 20 mg

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 209200, Israel

This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.



Omeprazole
Delayed Release Tablets 20 mg

Safety Feature - Do not use if printed tablet blister unit is open or torn.

NDC 0000-000-00

Compare to Prilosec OTC®*
FDA Approved

Treats FREQUENT Heartburn!

24 HR

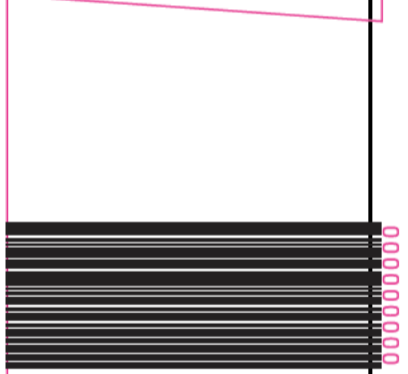
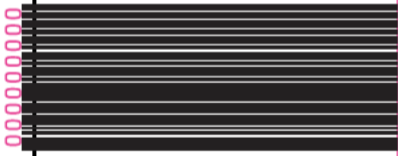
Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 and 6.6 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

NDC 0100-010-01

Compare to Prilosec OTC[®]*

3 PACK

**Three 14-day courses
of treatment**

Treats FREQUENT Heartburn!



Omeprazole

Delayed Release Tablets 20 mg Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

**COOL MINT
Coated Tablet**



47K55 PA C1-A 071621

Drug Facts (continued)

Active ingredient (in each tablet) Omeprazole 20 mg acid reducer

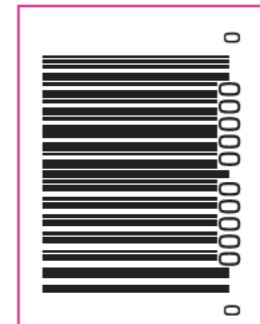
Purpose Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions For adults 18 years of age and older: Take one 1 tablet with a meal, once a day for 14 days. If you are taking a delayed release tablet, do not chew, crush, or suck the tablet. Do not take more than 1 tablet a day. Do not use for more than 14 days unless directed by your doctor. Request 14-Day Course (if needed) a swallow whole. Do not chew, crush, or suck tablets.

Warnings Do not use if you have: trouble swallowing food, vomiting with blood, or blood or black stools. Do not use if you have: a sore throat, difficulty swallowing, or pain when swallowing. Do not use if you have: a fever, rash, or other symptoms of an allergic reaction. Do not use if you are allergic to omeprazole. **Use** Do not use if you are allergic to omeprazole. Do not use if you have: trouble swallowing food, vomiting with blood, or blood or black stools. Do not use if you have: a sore throat, difficulty swallowing, or pain when swallowing. Do not use if you have: a fever, rash, or other symptoms of an allergic reaction. Do not use if you are allergic to omeprazole.

Other information Keep the can, 1, contents in original container. Do not use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs. Stop use and ask a doctor if you: experience symptoms of low magnesium, such as muscle spasms, dizziness, or weakness. Do not use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

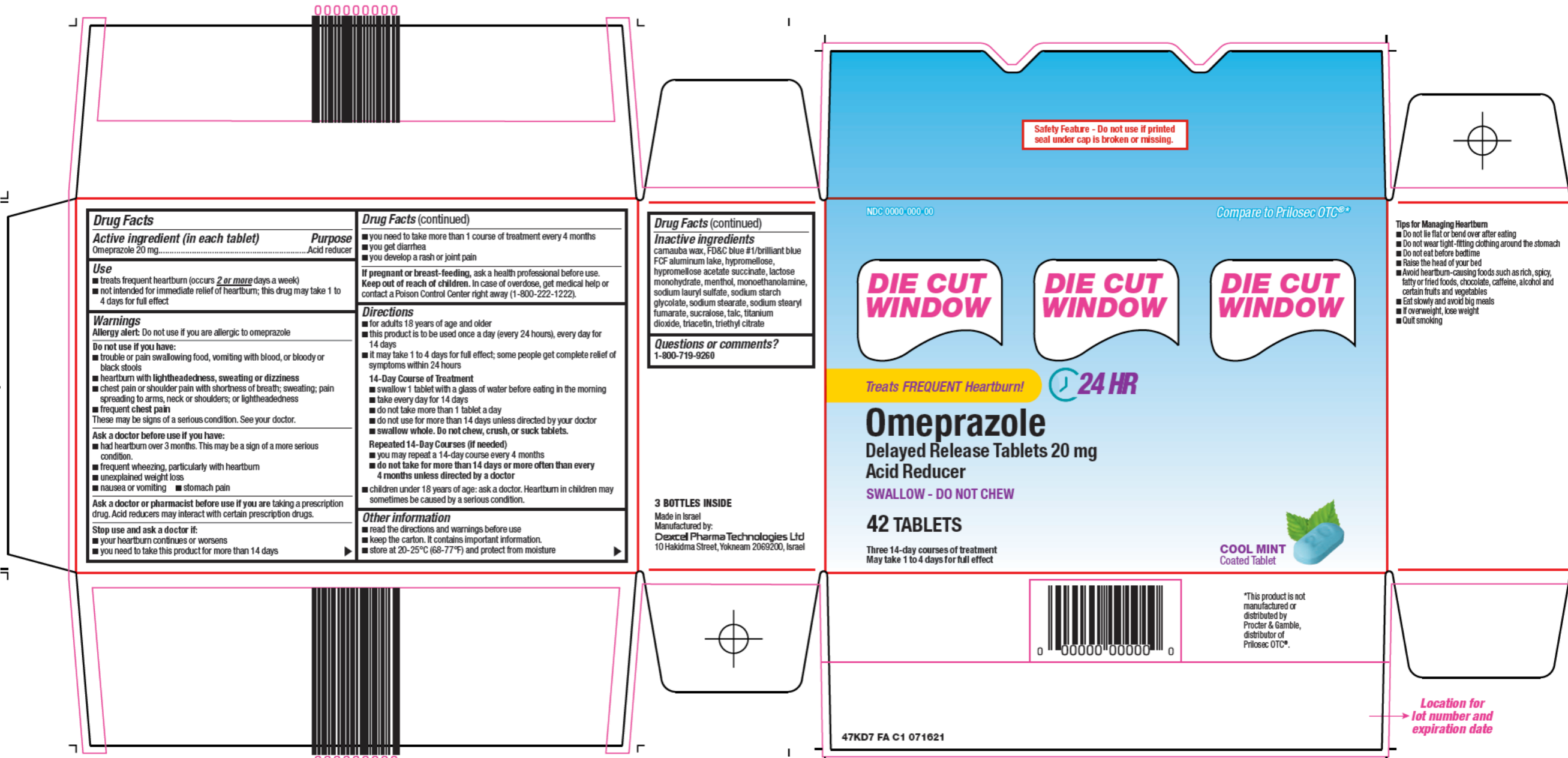
Questions or comments? 1-800-719-9280



Location for lot number and expiration date

**PRINT at 65% for
11-inch x 17-inch
size paper**

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TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.7 and 6.9 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	2 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000.000.00

Compare to Prilosec OTC®

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

24 HR

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect



COOL MINT
Coated Tablet

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.



47KD7 FA C1 071621

Location for lot number and expiration date

Drug Facts
Active ingredient (in each tablet)
Omeprazole 20 mg.....
Purpose
Acid reducer

Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days

Drug Facts (continued)
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)
Inactive ingredients
carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

3 BOTTLES INSIDE
Made in Israel
Manufactured by:
Dexel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000 000 00

Compare to Prilosec OTC[®]*

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

24 HR

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....**Purpose**
Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients

carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

3 BOTTLES INSIDE

Made in Israel
Manufactured by:
Dexel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC[®].

47KD7 FA C1-B 071921

Location for lot number and expiration date

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000-000-00

Compare to Prilosec OTC®*

Bonus! 14 Free



Treats FREQUENT Heartburn! 24 HR

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 ~~28~~ TABLETS

Three ~~two~~ 14-day courses of treatment
May take 1 to 4 days for full effect



COOL MINT
Coated Tablet

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD7 FA C1-E 071921

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....

Purpose
Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

 These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
 carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

3 BOTTLES INSIDE
 Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd
 10 Hakidma Street, Yokneam 2069200, Israel

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000 0000-00

Compare to Prilosec OTC®*

Bonus Pack! 14 Free

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!



Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect



COOL MINT
Coated Tablet

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg..... Acid reducer

Purpose
Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

- Allergy alert:** Do not use if you are allergic to omeprazole
- Do not use if you have:**
- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - heartburn with lightheadedness, sweating or dizziness
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent chest pain
- These may be signs of a serious condition. See your doctor.
- Ask a doctor before use if you have:**
- had heartburn over 3 months. This may be a sign of a more serious condition.
 - frequent wheezing, particularly with heartburn
 - unexplained weight loss
 - nausea or vomiting
 - stomach pain
- Ask a doctor or pharmacist before use if you are taking a prescription drug.** Acid reducers may interact with certain prescription drugs.
- Stop use and ask a doctor if:**
- your heartburn continues or worsens
 - you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
 - this product is to be used once a day (every 24 hours), every day for 14 days
 - it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
- 14-Day Course of Treatment**
- swallow 1 tablet with a glass of water before eating in the morning
 - take every day for 14 days
 - do not take more than 1 tablet a day
 - do not use for more than 14 days unless directed by your doctor
 - swallow whole. Do not chew, crush, or suck tablets.
- Repeated 14-Day Courses (if needed)**
- you may repeat a 14-day course every 4 months
 - do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-719-9260

3 BOTTLES INSIDE

Made in Israel
Manufactured by:
Dexel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD7 FA C1-D 071921

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Safety Feature - Do not use if printed seal under cap is broken or missing.

Drug Facts**Active ingredient (in each tablet)**

Omeprazole 20 mg.....Acid reducer

Purpose

Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - heartburn with **lightheadedness, sweating or dizziness**
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent **chest pain**
- These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)**Inactive ingredients**

carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-719-9260

3 BOTTLES INSIDE

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

NDC 0000-0000-00

Compare to Prilosec OTC®*

FDA Approved**DIE CUT WINDOW****DIE CUT WINDOW****DIE CUT WINDOW**

Treats FREQUENT Heartburn!



Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

47KD7 FA C1-F 071921

FORMAT: STANDARD**TYPE SIZES:**

TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....**Purpose**
Acid reducer

Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days

Drug Facts (continued)

■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

3 BOTTLES INSIDE
Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Safety Feature - Do not use if printed seal under cap is broken or missing.

NDC 0000-000-00

Compare to Prilosec OTC®**

3 PACK Three 14-day courses of treatment

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

24 HR

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



Tips for Managing Heartburn
■ Do not lie flat or bend over after eating
■ Do not wear tight-fitting clothing around the stomach
■ Do not eat before bedtime
■ Raise the head of your bed
■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
■ Eat slowly and avoid big meals
■ If overweight, lose weight
■ Quit smoking



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

47KD7 FA C1-A 071921

Location for lot number and expiration date

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
(continued)	8 pt Helvetica Neue LT Std 57 Condensed
HEADINGS	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
SUBHEADINGS	6 pt Helvetica Neue LT Std 77 Bold Condensed
TEXT	6 pt Helvetica Neue LT Std 57 Condensed
LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
TELEPHONE #	6 pt Helvetica Neue LT Std 77 Bold Condensed
HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box



Safety Feature - Do not use if printed seal under cap is broken or missing.

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....

Purpose
Acid reducer

Use
 ■ treats frequent heartburn (occurs **2 or more** days a week)
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with **lightheadedness, sweating or dizziness**
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days

Drug Facts (continued)

■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea
 ■ you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
 ■ for adults 18 years of age and older
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment
 ■ swallow 1 tablet with a glass of water before eating in the morning
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ swallow whole. Do not chew, crush, or suck tablets.

Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
 ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
 carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
 1-800-719-9260

3 BOTTLES INSIDE
 Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakidma Street, Yokneam 2069200, Israel

NDC 0000-000-00

Compare to Prilosec OTC®*

28 + 14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats **FREQUENT** Heartburn!



Omeprazole
 Delayed Release Tablets 20 mg
 Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
 May take 1 to 4 days for full effect

COOL MINT
 Coated Tablet



Tips for Managing Heartburn
 ■ Do not lie flat or bend over after eating
 ■ Do not wear tight-fitting clothing around the stomach
 ■ Do not eat before bedtime
 ■ Raise the head of your bed
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 ■ Eat slowly and avoid big meals
 ■ If overweight, lose weight
 ■ Quit smoking



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47KD7 FA C1-C 071921

Location for lot number and expiration date

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
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LEADING	6.5 pt
BULLETS	5 pt ITF Zapf Dingbats (square) with 2 ems (MM) spacing between statements
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HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

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Safety Feature - Do not use if printed seal under cap is broken or missing.

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....**Purpose**
Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
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- do not take more than 1 tablet a day
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Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients

carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

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Safety Feature - Do not use if printed seal under cap is broken or missing.

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Safety Feature - Do not use if printed seal under cap is broken or missing.

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HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

47KD7 FA C1-J 071921



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Location for lot number and expiration date

Compare to Prilosec OTC®*

Value Pack! Three-14 Tablet Bottles

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer
SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking



NDC 0000-0000-00 Compare to Prilosec OTC®*

Triple Pack Three 14-day courses of treatment

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats FREQUENT Heartburn!

Omeprazole

Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not wear tight-fitting clothing around the stomach
 - Do not eat before bedtime
 - Raise the head of your bed
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

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47KD7 FA C1-G 071921

Location for lot number and expiration date

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Drug Facts (continued)

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

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- do not take more than 1 tablet a day
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Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients

carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

3 BOTTLES INSIDE

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

0 00000 00000 0

FORMAT: STANDARD	
TYPE SIZES:	
TITLE	9 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
TITLE (continued)	8 pt Helvetica Neue LT Std 77 Bold Condensed Oblique
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HEAVY LINES	1.5 pt
HAIRLINES	0.5 pt Extend to within 2 spaces of the "Drug Facts" box

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

NDC 0000 000-00

Treats FREQUENT Heartburn!

 **24 HR**

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

14 TABLETS

One 14-day course of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



47K74 FA CP1 071621

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
14 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: L. Perrigo Company @1565), NCH Marketing, PO Box 880001, El Paso, TX 88688-0001

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



Omeprazole

Delayed Release Tablets 20 mg

14 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

FRONT PANEL

post-off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to
Prilosec OTC[®]*

NDC 0000-000-00

Treats FREQUENT Heartburn!

 **24 HR**

Omeprazole
Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

14 TABLETS

One 14-day course of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet

47KD5 FA CP1 071921



BACK PANEL

SAVE \$X NOW!

Omeprazole
Delayed Release
Tablets 20 mg

14 TABLETS

*This product is not
manufactured or distributed by
Procter & Gamble, distributor
of Prilosec OTC[®].

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your purchase of
14 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per
purchase. RETAILER: This coupon will be
redeemable for face value on specified products
(plus a handling fee) if
submitted in compliance
with the terms of this offer.
Cash value 1/100th of one
cent. Limit one coupon per
customer. Do Not Double.
Coupons are non-reproducible.
Coupons cannot be combined.

Mail properly handled
coupons to: L. Perrigo
Company #81565, NCH
Marketing, PO Box 880004,
El Paso, TX 79888-0001

**COUPON NOT SUBJECT
TO DOUBLING**
Customer pays any sales tax.



FRONT PANEL

Peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

NDC 0000-000-00

Treats **FREQUENT** Heartburn!



Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 TABLETS

Two 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



47K30 FA CP1 071621

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your purchase of
28 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: L. Perrigo Company (#1565), NCH Marketing, PO Box 880001, El Paso, TX 88588-0001

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



Omeprazole

Delayed Release Tablets 20 mg

28 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

FRONT PANEL

end of coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 0000-000-00

Treats FREQUENT Heartburn!

 **24 HR**

Omeprazole

Delayed Release Tablets 20 mg
Acid Reducer

SWALLOW - DO NOT CHEW

28 TABLETS

Two 14-day courses of treatment
May take 1 to 4 days for full effect



COOL MINT
Coated Tablet

47KD6 FA CP1 071921

BACK PANEL

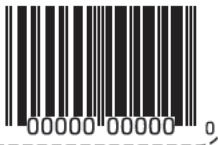
SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX} on your purchase of
28 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: L. Perrigo Company (#1565), NCH Marketing, PO Box 880001, El Paso, TX 88588-0001

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



Omeprazole

Delayed Release Tablets 20 mg

28 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

NDC 0000-000-00

Treats FREQUENT Heartburn!

 **24 HR**

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment

May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



47K55 FA CP1 071621

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
42 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: L. Penigo Company (8155), NCH Marketing, PO Box 680001, El Paso, TX 88568-0001

COUPON NOT SUBJECT TO DOUBLING

Customer pays any sales tax.



Omeprazole

Delayed Release Tablets 20 mg

42 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

FRONT PANEL

Best of
Coupons

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 0000 000 00

Treats FREQUENT Heartburn!

 **24 HR**

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 TABLETS

Three 14-day courses of treatment
May take 1 to 4 days for full effect

COOL MINT
Coated Tablet



47KD7 FA CP1 071921

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
42 COUNT SIZE

*Store Brand™ Omeprazole
Delayed Release Tablets 20 mg

COUPON NOT SUBJECT

TO DOUBLING

Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if distributed in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupon cannot be combined. Must properly handle coupons to: L. Perrigo Company (81565), NCH Marketing, PO Box 38304, El Paso, TX 79808-0001 0



Omeprazole

Delayed Release Tablets 20 mg

42 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

LABELING REVIEW(S)

LABEL AND LABELING REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	September 10, 2021
Requesting Office or Division:	Division of Nonprescription Drugs 1 (DNP1)
Application Type and Number:	NDA 022032/S-052
Product Name, Dosage Form, and Strength:	Omeprazole Delayed Release Tablets, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Over-the-Counter (OTC)
Applicant/Sponsor Name:	Dexcel Pharma Technologies Ltd
FDA Received Date:	June 2, 2021, July 26, 2021, and August 12, 2021
OSE RCM #:	2021-1283
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP

1 REASON FOR REVIEW

Dexcel Pharma Technologies Ltd (Dexcel) submitted a CMC supplement for omeprazole delayed release tablets, 20 mg, that adds a “cool mint” flavor formulation. Dexcel states that the new cool mint flavor formulation is identical to the approved wildberry formulation (b) (4) and the proposed tablet is blue-colored.

Subsequently, the Division of Nonprescription Drugs 1 (DNPD1) requested that we review the proposed omeprazole delayed release tablets, 20 mg, container labels and carton labeling for areas of vulnerability that may lead to medication errors.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
Human Factors Study	C – N/A
ISMP Newsletters*	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F
Labels and Labeling	G

N/A=not applicable for this review

*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We reviewed the proposed omeprazole delayed release tablets, 20 mg, container labels and carton labeling.

Currently, omeprazole delayed release tablets, 20 mg, under NDA 022032 are approved as an unflavored tablet and wildberry mint flavored tablet. Similar to the current wildberry mint flavor formulation that contains a wildberry image designating the flavor, the proposed cool mint flavor formulation container label and carton labeling contain an image of the blue tablet with two mint leaves and the corresponding statement “Cool Mint” in the bottom left corner of the Principal Display Panel (PDP). From a medication error perspective, we have no concerns related to these changes but provide a recommendation in Section 4.1 to ensure that the tablet image is reflective of the actual tablet on the container label (14-count bottle) and carton labeling. Additionally, we note that the statement “Actual Size” appears only on the inner

blister carton labeling, thus, [REDACTED]

(b) (4)

The blister card container labels contain the additional statement, “Coated with cool mint flavor” that appears above the established name. This statement describes the cool mint flavor formulation, and we find its addition reasonable.

There are no changes to the *Directions* section of the Drug Facts Label (DFL).

We note that the proposed container labels and carton labeling contain a placeholder for the lot number and expiration date, but the format for the expiration date is not provided. Thus, to ensure the safe use of the product and to minimize confusion and risk for deteriorated drug medication errors, we provide a recommendation in Section 4.1.

4 CONCLUSION & RECOMMENDATIONS

We conclude that the omeprazole delayed release tablets proposed container labels and carton labeling and may be improved to minimize confusion and risk for deteriorated drug medication errors and to ensure safe use of the proposed product. Therefore, we provide recommendations in Section 4.1.

4.1 RECOMMENDATIONS FOR DEXCEL PHARMA TECHNOLOGIES LTD

We recommend the following be implemented prior to approval of this NDA Supplement:

A. Container Labels and Carton Labeling

1. Ensure that the tablet graphic image for the omeprazole delayed release tablets presented on the carton labeling represents a true depiction of the actual tablet. Ensure the image reflects the true tablet size, color, and imprint of the actual tablet.
2. The statement, “Actual Size” appears only on the 14-count blister inner carton labeling. [REDACTED] (b) (4)
3. As currently presented in the proposed container labels and carton labeling, the format for the expiration date is not defined. To reduce the risk for deteriorated drug medication errors, ensure you identify the format you intend to use. FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format, if only numerical characters are used, or in YYYY-MMM-DD format, if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable

text may include only a year and month, to be expressed as, YYYY-MM, if only numerical characters are used, or YYYY-MMM, if alphabetical characters are used to represent the month. FDA recommends that a slash or a hyphen be used to separate the portions of the expiration date.

APPEARS THIS WAY ON ORIGINAL



APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Omeprazole Delayed Release Tablets received on July 26, 2021 from Dexcel Pharma Technologies Ltd, and the listed drug (LD).

Table 2. Relevant Product Information for Omeprazole Delayed Release Tablets and the Listed Drug		
Product Name	Omeprazole Delayed Release Tablets	Prilosec OTC ^a
Initial Approval Date	December 4, 2007	June 20, 2003
Active Ingredient	Omeprazole	Omeprazole
Indication	Drug Facts label (DFL) <i>Use</i> : <ul style="list-style-type: none"> ▪ treats frequent heartburn (occurs 2 or more days a week) ▪ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect 	Drug Facts label (DFL) <i>Use</i> : <ul style="list-style-type: none"> ▪ treats frequent heartburn (occurs 2 or more days a week) ▪ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Route of Administration	Oral	Oral
Dosage Form	Delayed release tablets	Delayed release tablets
Strength	20 mg	20 mg

^a Prilosec OTC [Drug Facts Label] NDA 021229. Drugs@FDA. U.S. Food and Drug Administration. 2020 JAN 30. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021229s034lbl.pdf.

Table 2. Relevant Product Information for Omeprazole Delayed Release Tablets and the Listed Drug

Product Name	Omeprazole Delayed Release Tablets	Prilosec OTC ^a
Dose and Frequency	<p><i>DFL Directions:</i></p> <ul style="list-style-type: none"> ▪ for adults 18 years of age and older ▪ this product is to be used once a day (every 24 hours), every day for 14 days ▪ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ▪ swallow 1 tablet with a glass of water before eating in the morning ▪ take every day for 14 days ▪ do not take more than 1 tablet a day ▪ do not use for more than 14 days unless directed by your doctor ▪ (b) (4) Do not chew or crush tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ▪ you may repeat a 14-day course every 4 months ▪ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ▪ children under 18 years of age: ask a doctor. (b) (4) 	<p><i>DFL Directions:</i></p> <ul style="list-style-type: none"> ▪ for adults 18 years of age and older ▪ this product is to be used once a day (every 24 hours), every day for 14 days ▪ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ▪ swallow 1 tablet with a glass of water before eating in the morning ▪ take every day for 14 days ▪ do not take more than 1 tablet a day ▪ do not use for more than 14 days unless directed by your doctor ▪ swallow whole. Do not chew or crush tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ▪ you may repeat a 14-day course every 4 months ▪ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>
How Supplied	2-count tablets (sample) 14-count blister 14-count carton – blister and bottle 28-count carton – blister and bottle 42-count carton – blister and bottle	2-count tablets (sample) 14-count blister 14-count carton (also in wildberry flavor) 28-count carton 42-count carton (also in wildberry flavor)
Storage	store at 20-25°C (68-77°F) and protect from moisture	store at 20-25°C (68-77°F) and protect from moisture

APPENDIX B. PREVIOUS DMEPA REVIEWS

On August 9, 2021, we searched for previous DMEPA reviews relevant to this current review using the terms, omeprazole and 022032. Our search did not identify previous reviews.

APPEARS THIS WAY ON ORIGINAL



APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,^b along with postmarket medication error data, we reviewed the following Omeprazole Delayed Release Tablets labels and labeling submitted by Dexcel Pharma Technologies Ltd.

- Container labels received on August 12, 2021 (blister card)
- Carton labeling received on July 26, 2021

G.2 Label and Labeling Images

^b Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GRACE JONES
09/10/2021 02:49:06 PM

ASHLEIGH V LOWERY
09/10/2021 03:12:02 PM

Labeling Review for Omeprazole Delayed Release Tablets, 20 mg *Draft Labeling*

SUBMISSION DATES:	June 2, 2021 July 26, 2021 August 12, 2021
NDA/SUBMISSION TYPE:	022032, S-052/CMC + Labeling Prior Approval Supplement
ACTIVE INGREDIENT:	Omeprazole, 20 mg
DOSAGE FORM:	Delayed Release Tablets
APPLICANT:	Dexcel Pharma Technologies Ltd. U.S. Agent: ICON Clinical Research LLC
REVIEWER:	Lori Parsons, PhD, ONPD/DNPD I
TEAM LEADER:	Kevin Lorick, PhD, ONPD/DNPD I

I. BACKGROUND

New Drug Application (NDA) 022032 (omeprazole delayed release tablets (DRT), 20 mg) is a 505(b)(2) application approved on December 4, 2007, for the nonprescription treatment of frequent heartburn (occurring two or more days a week) in adults 18 years of age and older. The listed drug for this 505(b)(2) application is Prilosec OTC (omeprazole magnesium DRT, 20.6 mg), NDA 021-229, approved on June 20, 2003. Dexcel's omeprazole drug product is marketed in unflavored and wildberry mint flavored DRT. The drug product marketed under NDA 022032 does not have a proprietary name. Instead, this drug product is marketed using the established name of the active ingredient, omeprazole.

Per the June 20, 2003 approval letter of the first nonprescription PPI, NDA 021229 (omeprazole DRT/Prilosec OTC), all nonprescription PPIs have a package size limitation on individual containers not being greater than 14-count (single treatment course) and total package sizes no greater than 42-count (three treatment courses, or one year of treatment).¹ Package sizes greater than the above-mentioned quantities are expected to submit a prior approval supplement (PAS) that includes data to demonstrate consumer comprehension of the limitations of use.

¹ See the NDA 021229/Prilosec OTC (omeprazole magnesium delayed release tablets) approval letter dated June 20, 2003, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/021229ltr_Prilosec.pdf.

There are eighty-two approved labeling components associated with this NDA, including immediate container labels (e.g., 14-count bottle and blister configurations), outer carton labeling (14-, 28-, and 42-count configurations), inner carton labeling (14-count configuration), multiple bonus outer carton labeling (i.e., “14 FREE” flags on 28- and 42-count configurations), and multiple instantly redeemable coupons (IRCs). See the labeling review for supplement 038 dated October 26, 2017 (archived in Document Archiving, Reporting and Regulatory Tracking System (DARRTS)) for details on the full list of currently approved labeling. The most recently approved labeling is from supplement 046, approved on July 7, 2021, and provided for the following:

- 14- and 28-count omeprazole DRT outer carton labeling accompanied with an in-pack coupon for a free 14-count omeprazole delayed release orally disintegrating tablets (DR ODT) product at the next purchase
- 14- and 28-count omeprazole DRT outer carton labeling accompanied with an in-pack coupon for \$X OFF the next purchase of a 14-count omeprazole DR ODT product
- 14- and 28-count principal display panel (PDP) partial replica (omeprazole DRT) IRC
- 14- and 28-count folded IRC for a FREE 14-count omeprazole DR ODT

(b) (4)

Supplement 052 (S-052), submitted on June 2, 2021, is a CMC + Labeling PAS that proposes an additional of mint flavored formulation termed cool mint in the labeling and 43 new labeling components (36 immediate container/outer carton labeling; and 6 IRCs) highlighting the cool mint flavor on the PDP. This new cool mint formulation (b) (4) relative to the approved wildberry mint formulation under the same NDA, NDA 022032. Note, Dexcel failed to submit the 2-count immediate container label that corresponds with the proposed cool mint 2-count outer carton in the original June 2, 2021 and July 26, 2021 amendment submissions. DNPDI worked with Dexcel to submit this labeling component (see details on August 12, 2021 IR response below).

An information request (IR) was sent to Dexcel during the review of sNDA 022032/052 by this reviewer on July 1, 2021, which recommended four labeling improvement considerations to better support consumer messaging around qualities of this drug product.

1. Consider removing the boldface type on “Frequent” in the statement “Treats Frequent Heartburn!” on the principal display panel (PDP) to ensure that the word “Frequent” does not overshadow the statement “Treats Frequent Heartburn!”
2. We recommend applying boldface type to the number of treatment courses statement below the declaration of net quantity (e.g., “One 14-day course of treatment”).
3. We recommend increasing the prominence of the nonprescription proton pump inhibitor class labeling statement “May take 1 to 4 days for full effect” to be as large as the statement “One 14-day course of treatment” in the lower third portion of the PDP. We also recommend using boldface type.

4. Consider using a different font color on the promotional statements displayed in (b) (4) text on a light blue background (e.g., “Bonus Pack! 14 Free,” “Triple Pack Three 14-day courses of treatment”, etc.) to improve the contrast and readability.

Dexcel responded to this IR on July 26, 2021 by submitting 42 revised labeling components that implemented all four labeling considerations proposed by DNPDI. A follow up IR was sent to Dexcel on August 8, 2021 requesting the submission of 2-count immediate container (blister) label because it appeared to be missing from the June 2, 2021 and July 26, 2021 amendment submissions. DNPDI noted that a labeling file submitted by Dexcel entitled cm-blister foil in the July 26, 2021 amendment submission appeared to be a duplicate of the labeling file entitled cm-14ct-blister-carton. Dexcel responded on August 12, 2021 by submitting the 2-count immediate container (blister) label. Dexcel also submitted ten labeling files which relate to a previously approved PAS, S-046.

Submitted Labeling	Date Submitted
Cool Mint Flavored Tablets	
2-count immediate container (physician sample)	August 12, 2021
14-count immediate container (blister)	June 2, 2021 Resubmitted: August 12, 2021
14-count immediate container (bottle)	June 2, 2021 Revised: July 26, 2021
14-count inner carton	June 2, 2021 Revised: July 26, 2021
2-count outer carton (physician sample)	June 2, 2021 Revised: July 26, 2021
14-count outer carton (blister)	June 2, 2021 Revised: July 26, 2021
14-count outer carton with the “FDA Approved” statement (blister)	June 2, 2021 Revised: July 26, 2021
14-count outer carton (bottle)	June 2, 2021 Revised: July 26, 2021
14-count outer carton with the “FDA Approved” statement (bottle)	June 2, 2021 Revised: July 26, 2021
28-count outer carton (blister)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the “14 Free” statement (blister)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the “Bonus! 14 Free” statement (blister)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the “Bonus Pack! 14 Free” statement (blister)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the “FDA Approved” statement (blister)	June 2, 2021 Revised: July 26, 2021
28-count outer carton (bottle)	June 2, 2021 Revised: July 26, 2021

28-count outer carton with the "14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the "Bonus! 14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
28-count outer carton with the "FDA Approved" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "14 Free" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Bonus! 14 Free" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Bonus Pack! 14 Free" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "FDA Approved" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "28 + 14 FREE" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Value Pack! Three- Tablet Cartons" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Triple Pack Three 14-day courses of treatment" statement (blister)	June 2, 2021 Revised: July 26, 2021
42-count outer carton (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Bonus! 14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "FDA Approved" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "28 + 14 FREE" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Value Pack! Three- 14 Tablet Bottles" statement (bottle)	June 2, 2021 Revised: July 26, 2021
42-count outer carton with the "Triple Pack Three 14-day courses of treatment" statement (bottle)	June 2, 2021 Revised: July 26, 2021

14-count IRC (blister)	June 2, 2021 Revised: July 26, 2021
14-count IRC (bottle)	June 2, 2021 Revised: July 26, 2021
28-count IRC (blister)	June 2, 2021 Revised: July 26, 2021
28-count IRC (bottle)	June 2, 2021 Revised: July 26, 2021
42-count IRC (blister)	June 2, 2021 Revised: July 26, 2021
42-count IRC (bottle)	June 2, 2021 Revised: July 26, 2021

The proposed labeling was compared to the most currently approved labeling (wildberry flavor) from NDA 022032/S-041, approved on April 8, 2019. The wildberry flavor tablet labeling is the comparator, and not the unflavored tablet labeling because the proposed cool mint tablets involve (b) (4) **Importantly, similar to** the wildberry flavored tablets, the cool mint flavored tablets (b) (4) that also involve specific labeling statements informing the consumer to swallow tablets whole (found on the PDP) and “[bullet] swallow whole. Do not chew, crush, or suck tablets.” (found in the Directions heading of the DFL). (b) (4)

The unflavored tablets under this NDA do not have labeling statements telling the consumer to not suck the tablets. Instead, the unflavored tablets product contains the labeling statements (b) (4) “Do not chew or crush tablets.”

II. REVIEWER'S COMMENTS

- A. 2-, 14-, 28, 42-count (blister and bottle) outer carton labeling, 14-, 28-, and 42-count outer carton with the “FDA Approved” statement (blister and bottle), 28- and 42-count outer carton with the “14 Free” statement (blister and bottle), 28- and 42-count outer carton with the “Bonus! 14 Free” statement (blister and bottle), 28- and 42-count outer carton with the “Bonus Pack! 14 Free” statement (blister and bottle), 42-count outer carton with the “3 PACK Three 14-day courses of treatment” statement (blister and bottle), 42-count outer carton with the “28 + 14 FREE” statement (blister and bottle), 42-count outer carton with the “Value Pack! Three- 14 Tablet Cartons”/ “Value Pack! Three- 14 Tablet Bottles” statement (blister/bottle), 42-count outer carton with the “Triple Pack Three 14-day courses of treatment” statement (blister and bottle)

i. Outer Carton Label Outside Drug Facts Label

- a. The statement “Cool Mint Coated Tablet” is added to the lower, right corner of the PDP. An image of blue tablet with “20” debossed on the front-facing tablet side appears below two mint leaves (b) (4) on light blue background.

Comment: The statement and image appear to be truthful and not misleading because the drug product is mint flavored, and the tablet is blue and contains

an imprint of “20” on one side. Also, the size of the tablet image appears to be of actual size (~11mm) using Dexcel’s submitted Description and Composition (eCTD file entitled “description-and-composition-2.pdf”) files submitted to the eCTD on June 2, 2021 (section 3.2.P.1: Description and composition of the drug product-2, page 3, Pictures section). This is acceptable.

- b. The boldface type on “Frequent” in the statement “Treats Frequent Heartburn!” is removed. This statement appears on the PDP above the statement of identity.

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 requested that Dexcel consider removing the boldface type on “Frequent” in the statement “Treats Frequent Heartburn!” on the PDP to ensure that the word “Frequent” does not overshadow the statement “Treats Frequent Heartburn!” Dexcel implemented the revision to remove the boldface type from “Frequent” in the statement “Treats Frequent Heartburn!” on the PDP (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- c. Boldface type is applied to the number of treatment courses statement below the declaration of net quantity (e.g., “One 14-day course of treatment”).

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 recommended applying boldface type to the number of treatment courses statement below the declaration of net quantity (e.g., “One 14-day course of treatment”). Dexcel implemented the revision to apply boldface type to this nonprescription proton pump inhibitor (PPI) class labeling statement as recommended (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- d. The prominence of the nonprescription PPI class labeling statement “May take 1 to 4 days for full effect” is increased to be as large as the statement “One 14-day course of treatment” in the lower third portion of the PDP. Boldface type is applied.

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 recommended applying boldface type and increasing the prominence of the nonprescription PPI class labeling statement “May take 1 to 4 days for full effect” to be as large as the statement “One 14-day course of treatment” in the lower third portion of the PDP. Dexcel implemented the revision as recommended (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- e. The font color used to display the promotional statements (e.g., “Bonus Pack! 14 Free,” “Triple Pack Three 14-day courses of treatment”, etc.) have changed from (b) (4) font on a light blue background to dark blue font on a light blue background.

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 recommended that Dexcel consider using a different font color on the promotional statements displayed in (b) (4) text on a light blue background (e.g., “Bonus Pack! 14 Free,” “Triple Pack Three 14-day courses of treatment”, etc.) to improve the contrast and readability. Dexcel implemented the revision as recommended (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

ii. Outer Carton Label Outside Drug Facts Label

- a.** The labeling meets format specifications set forth in 21 CFR 201.66.

Comment: This is acceptable.

- b.** The listing of inactive ingredients in the DFL have changed. The previously approved wildberry mint coated tablets (NDA 22032) labeling includes the following inactive ingredients: benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, avor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate. The cool mint coated tablet labeling includes the following inactive ingredients: carnauba wax, FD&C blue #1/brilliant blue FCF aluminum lake, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, monoethanolamine, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate.

Comment: This is acceptable from a labeling perspective with concurrence from CMC and nonclinical accepting and recommending approval of the formulation and flavor change involved with the cool mint flavored tablets.

B. 2-count Outer Carton (physician’s sample)

i. Outer Carton Label Outside Drug Facts Label

- a.** The statement “May take 1 to 4 days for full effect” is added to the lower, left corner of the PDP in boldface type.

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 advised Dexcel to add the nonprescription PPI class labeling statement “May take 1 to 4 days for full effect” in boldface type to the 2-count outer carton labeling. Dexcel implemented the revision as advised (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- b. Boldface type is applied to the statement “First 2 doses of 14-day course of treatment” located on the PDP.

Comment: An IR from DNPDI sent to Dexcel on July 1, 2021 advised Dexcel to apply boldface type to the statement “First 2 doses of 14-day course of treatment” to provide clarity to consumers on how the sample doses fit into the set treatment course for the drug product. Dexcel implemented the revision as advised (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- c. The statements “Read Drug Facts label on the back before trying” and “FREE SAMPLE INSIDE” appear in the upper left corner of the PDP in black font. The statement “NOT FOR SALE” appears on the top panel of the outer carton in black boldface type.

Comment: This is acceptable. It is always acceptable to refer the consumer to the DFL because this labeling content contains complete information about safe and effective use of a drug product and does not contain promotional content. Free samples are acceptable in the nonprescription setting, although ONPD does not have a working definition of a sample. This reviewer finds FDA’s definition of sample in the prescription setting compelling, where a prescription drug sample as a unit of drug not intended for sale and intended to promote the sale of the drug product.² This proposal meets the prescription definition. Importantly, the sample labeling contains all the same and complete labeling content as the full, standard of therapy. The only differences in labeling are PDP text referencing the sample and detailed in II.B.i.a. above. A 2-count sample configuration has been previously approved for nearly all nonprescription PPIs.

- d. The statement “NDC 000-00-000-00” is added to the upper, right corner of the PDP.

Comment: This is acceptable. The NDC number is requested and not required under 21 CFR 201.2.

- e. See sections of II.A.i.a-e.

C. 14-count Inner Carton

i. Outer Carton Label Outside Drug Facts Label

- a. See sections of II.A.i.a-e.

- b.

(b) (4)

² 21 U.S.C. 353(c).

(b) (4)

- b. Boldface type is applied to the entire declaration of net quantity of contents statement, including “TABLETS”.

Comment: The declaration of net quantity shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface under 21 201.62(g). An IR from DNPDI dated July 1, 2021 advised Dexcel to apply boldface type to the entire declaration of net quantity of contents statement, including “TABLETS” under 21 201.62(g). Dexcel implemented the revision as advised (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

- c. Boldface type is applied to the entire statement of identity including, “Delayed Release Tablets 20 mg” on the PDP.

Comment: This is acceptable. The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed under 21 CFR 201.61(c). An IR from DNPDI dated July 1, 2021 advised Dexcel to apply boldface type to the entire statement of identity including, “Delayed Release Tablets 20 mg” on the PDP, per 21 CFR 201.61(c). Dexcel implemented the revision as advised (see the IR response from Dexcel submitted to the eCTD dated July 26, 2021). This is acceptable.

D. 42-count outer carton labeling with a Value Pack statement

i. Outer Carton Label Outside Drug Facts Label

- a. See sections of II.A.i.a-e.
- b. The statement “Value Pack! 3 -14 Tablet Cartons” in the upper, right corner of the PDP is revised to state “Value Pack! Three -14 Tablet Cartons” on the blister packaging, or “Value Pack! Three- 14 Tablet Bottles”.

Comment: This is acceptable. An IR from DNPDI dated July 1, 2021 advised Dexcel to spell out “three” in the statement “Value Pack! 3 -14 Tablet Cartons” to avoid confusion with the quantity of product contents. As previously written, it could be read to express that this outer carton contains between three to fourteen tablet cartons, which would be inaccurate. The statement “Value Pack! Three -14 Tablet Cartons” and “Value Pack! Three-14 Tablet Bottles” better clarifies the contents within the packaging.

E. 2- and 14-count Immediate Container

- a. For the blister immediate container labels, the statement “Coated with cool mint flavor” is added on the top of each blister unit.

Comment: This is acceptable. See this reviewer’s comment in II.A.i.a.

- b. For the 14-count bottle immediate container label, the statement “COOL MINT Coated Tablet” and image of a blue tablet with a debossment “20” on the front-facing side below two mint leaves are added adjacent to the declaration of net quantity.

Comment: This is acceptable. See this reviewer’s comment in II.A.i.a.

F. 14-, 28-, 42-count (bottle and blister) IRCs

- a. A peel-off IRC with the front-side duplicating the PDP is proposed. The statements “peel off coupon” and “SAVE \$X now! On This Purchase” appear on the upper, right corner of the front-side of the peel-off IRC. The front-side of the IRC also contains the same content as that of the PDP of the drug product for which it is placed upon. All of the changes proposed in sections II.A.a-e. apply to the PDP. The backside of the IRC contains the terms and conditions of the IRC for the consumer and retailer, and the statements “SAVE \$X NOW!”, “Omeprazole Delayed Release Tablets 20 mg”, “14 TABLETS”, and “This product is not manufactured or distributed by Proctor & Gamble, distributor of Prilosec OTC®.”.

Comment: This is acceptable. The content matches the acceptable PDP. Additionally, the statements promoting the peel-off coupon appear truthful and not misleading, and do not interfere with the package size limitations for the class of nonprescription PPIs, which limit package sizes to no greater than 42-count without adequate consumer data demonstrating comprehension of the limitations of use. The proposed IRCs do not offer or promote the nonprescription PPI beyond 42-count. The content of the backside of the IRC appears to be truthful and not misleading.

Note, a social science analyst was included in the review meetings of this supplement.

III. RECOMMENDATION

Issue an **APPROVAL** letter to the Applicant for the submitted omeprazole delayed release tablets, 20 mg labeling and request final printed labeling. Request that the Applicant submit final printed labeling identical to the following labeling submitted on the following dates:

Cool Mint Flavored Tablets Label Submitted on August 12, 2021:

1. 2-count immediate container label

Cool Mint Flavored Tablets Labeling Submitted on July 26, 2021:

2. 14-count immediate container (blister)
3. 14-count immediate container (bottle)
4. 14-count inner carton
5. 2-count physician sample outer carton (blister)
6. 14-count outer carton (blister)
7. 14-count outer carton with the "FDA Approved" statement (blister)
8. 14-count outer carton (bottle)
9. 14-count outer carton with the "FDA Approved" statement (bottle)
10. 28-count outer carton (blister)
11. 28-count outer carton with the "14 Free" statement (blister)
12. 28-count outer carton with the "Bonus! 14 Free" statement (blister)
13. 28-count outer carton with the "Bonus Pack! 14 Free" statement (blister)
14. 28-count outer carton with the "FDA Approved" statement (blister)
15. 28-count outer carton (bottle)
16. 28-count outer carton with the "14 Free" statement (bottle)
17. 28-count outer carton with the "Bonus! 14 Free" statement (bottle)
18. 28-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)
19. 28-count outer carton with the "FDA Approved" statement (bottle)
20. 42-count outer carton (blister)
21. 42-count outer carton with the "14 Free" statement (blister)
22. 42-count outer carton with the "Bonus! 14 Free" statement (blister)
23. 42-count outer carton with the "Bonus Pack! 14 Free" statement (blister)
24. 42-count outer carton with the "FDA Approved" statement (blister)
25. 42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (blister)
26. 42-count outer carton with the "28 + 14 FREE" statement (blister)
27. 42-count outer carton with the "Value Pack! Three- 14 Tablet Cartons" statement (blister)
28. 42-count outer carton with the "Triple Pack Three 14-day courses of treatment" statement (blister)
29. 42-count outer carton (bottle)
30. 42-count outer carton with the "14 Free" statement (bottle)
31. 42-count outer carton with the "Bonus! 14 Free" statement (bottle)
32. 42-count outer carton with the "Bonus Pack! 14 Free" statement (bottle)
33. 42-count outer carton with the "FDA Approved" statement (bottle)
34. 42-count outer carton with the "3 PACK Three 14-day courses of treatment" statement (bottle)

35. 42-count outer carton with the “28 + 14 FREE” statement (bottle)
36. 42-count outer carton with the “Value Pack! Three- 14 Tablet Bottles” statement (bottle)
37. 42-count outer carton with the “Triple Pack Three 14-day courses of treatment” statement (bottle)
38. 14-count IRC (blister)
39. 14-count IRC (bottle)
40. 28-count IRC (blister)
41. 28-count IRC (bottle)
42. 42-count IRC (blister)
43. 42-count IRC (bottle)

Remind the Applicant that if they are interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14-count, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of use.

IV. SUBMITTED LABELING

The labels on the remaining pages of this labeling review were submitted and evaluated in this labeling review:

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORI N PARSONS
09/08/2021 11:13:39 AM

KEVIN L LORICK
09/08/2021 11:22:15 AM
I concur with the review and recommendations.

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

CHEMISTRY REVIEW(S)

Office of Lifecycle Drug Products
Division of Post-Marketing Activities I
Review of Chemistry, Manufacturing, and Controls

1. **NDA Supplement Number:** NDA 22032/S052

2. **Submission(s) Being Reviewed:**

Submission	Type	Submission Date	Assigned Date	PDUFA Goal Date	Review Date
Original	PAS	6/2/2021	6/9/2021	10/2/2021	9/14/2021

3. **Provides For:** Addition of a cool mint flavored formulation of Omeprazole Delayed Released Tablets, 20mg.

4. **Review 1:**

5. **Clinical Review Division:** OND/DNDP

6. **Name and Address of Applicant:**

Dexcel Pharma Technologies Ltd.

1 Dexcel Street

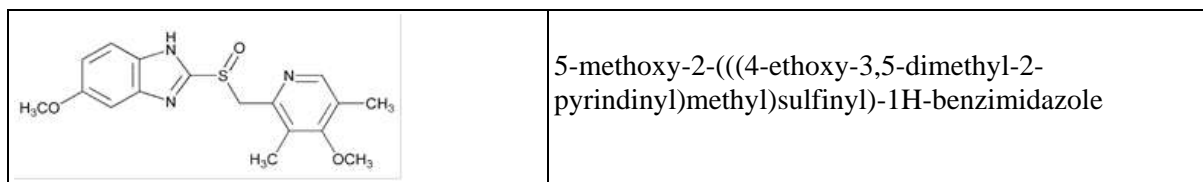
Or-Akiva, Israel 3060000

Israel

7. **Drug Product:**

Drug Name	Dosage Form	Strength	Route of Administration	Rx or OTC	Special Product
Omeprazole	Delayed-release tablet	20 mg	Oral	OTC	No

8. **Chemical Name and Structure of Drug Substance:**



9. **Indication:** For the treatment of frequent heartburn (occurring two or more days a week)

10. **Supporting/Relating Documents:**

11. **Consults:**

Consults	Recommendation	Date	Reviewer
OPMA/Facility			
DMF			
Microbiology			
Pharm/Tox	Approval	9/2/2021	Chibueze Ihunnah
Biopharm	Approval	9/10/2021	Min Sung Suh
Statistics			
DMEPA			
CDRH/ODE			
CDRH/OC			
EA			

12. Executive Summary:

OND Managed

This supplement provides for the addition of a cool mint flavored formulation of Omeprazole Delayed Released Tablets, 20mg.

The formulation of the Cool Mint flavored Omeprazole Delayed Released Tablets, 20mg is quantitatively and qualitatively the same as the current wildberry mint formulation. It differs from the wildberry mint flavored formulation in color (b) (4)

The new formulation introduced a new Blue Color (b) (4). Each component listed in the colorant formulation is in compliance with its associated CFR (172.874, 73.575, 73.1, 184.1901, 82.51 and 82.10) and is considered safe to be used in the drugs. It is noted that P/T does not evaluate color, only flavorant.

The applicant has provided comparative dissolution data and dissolution profiles of the proposed and approved formulations. Biopharm has reviewed data provided and has concluded that *in vitro* dissolution data provided shows that the proposed changes in color and flavor unlikely to impact dissolution and bioavailability (reviewed by Dr. Mn Sung Suh in Panorama on 9/10/2021).

The applicant has provided batch data and stability data of proposed Cool Mint flavored Omeprazole Delayed Released Tablets. Data provided support proposed new cool mint flavored drug product.

13. Conclusions & Recommendations:

This supplement is recommended for Approval from CMC perspective

14. Comments/Deficiencies to be Conveyed to Applicant: The following comment should be communicated to the sponsor via General Advice letter:

We recommend you update the naming of the following impurities as shown below for N22032 for the wildberry drug product to ensure harmonization for all the drug product flavors within this NDA.

Approved Wild-berry mint flavored product	Proposed Cool mint flavored product
(b) (4)	

15. Primary Reviewer:

Ping Jiang-Baucom, CMC reviewer, Branch 3, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ)

16. Secondary Reviewer:

Gurpreet Gill-Sangha, Branch Chief, Branch 3, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, OPQ

CMC ASSESSMENT

I BACKGROUND INFORMATION

Omeprazole Delayed Release Tablets, 20mg is an over-the-counter drug used for the treatment of frequent Heartburn. On March 6, 2015 the wildberry mint flavored product was approved by the FDA as a supplement. This supplement provides for the addition of a cool mint flavored formulation of Omeprazole Delayed Released Tablets, 20mg.

The formulation of the Cool Mint flavored Omeprazole Delayed Released Tablets, 20mg is quantitatively and qualitatively the same as the current wildberry mint formulation. It differs from the wildberry mint flavored formulation in color (b) (4)

The cool mint flavored formulation will be included in the same NDA and it is therapeutically equivalent to the current approved Omeprazole Delayed Release Tablets, 20mg.

II PROPOSED CHANGES

Addition of a cool mint flavored formulation of Omeprazole Delayed Released Tablets, 20mg.

III DATA SUBMITTED TO SUPPORT THE PROPOSED CHANGES

3.2.P.1 Description and Composition of the Drug Product, Introduction [Omeprazole Delayed Release Tablets, 20 mg, Cool Mint Flavored]

Unflavored Drug Product:

Omeprazole Delayed Release Tablets, 20 mg are brownish, capsule shaped film coated tablets, with a debossment "20" on one side.

Wildberry Mint Flavored Drug Product:

Omeprazole Delayed Release Tablets, 20 mg are purple, capsule shaped film coated tablets, with a berry like odor, with a debossment "20" on one side.

Cool Mint Flavored Drug Product:

Omeprazole Delayed Release Tablets, 20 mg are blue, capsule shaped film coated tablets, with a debossment "20" on one side.

Unit composition

Name of Constituent	Quantity per Tablet [mg]			Function of constituent	Grade
	Unflavored	Currently approved Wildberry Mint Flavored	Proposed Cool Mint Flavored		
					(b) (4)
Omeprazole	20.00	20.00	20.00	Drug substance	USP
Lactose Monohydrate				(b) (4)	NF
Sodium Starch Glycolate					NF
Sodium Stearate					NF
Sodium Stearyl Fumarate					NF
(b) (4)					
Hypromellose					NF
Acetate Succinate					
Talc					USP
Triethyl Citrate					NF
Monoethanolamine					NF
Sodium Lauryl Sulfate					NF
(b) (4)					(b) (4)
Menthol	(b) (4)				NF
(b) (4)					(b) (4)
Sucralose					NF
Carnauba wax					NF
Total weight	285.00	307.00	307.00		

Reviewers Evaluation: Acceptable

Compare to the currently approved Wildberry Mint flavored drug product, proposed Cool Mint flavored drug product (b) (4) Purple Color, have been replaced with a new Blue Color (b) (4). All other active and inactive ingredients remind unchanged. The total tablet weight is also remind unchanged.

The applicant has provided formulation of the proposed new Blue Color (b) (4) used as shown below:

Reviewers Evaluation: Acceptable

The only CMC related change for the draft label is section "Inactive ingredients" . inactive ingredients listed on the draft lable are confirmed. Proposed draft labeling are acceptable from CMC perspective.

(b) (4)

IV RISK ASSOCIATED WITH THE PROPOSED CHANGES AND IMPACT TO PRODUCT QUALITY AND PATIENT SAFETY

Low

APPEARS THIS WAY ON ORIGINAL



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Jiang-Baucom

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Gurpreet
Gill Sangha

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

BIOPHARMACEUTICAL REVIEW(S)

BIOPHARMACEUTICS ASSESSMENT*	
Application No.	NDA-022032-SUPPL-52
Submission Type	PAS
Submission Classification	CMC
Applicant	Dexcel Pharma Technologies Ltd
Product Name	Omeprazole Delayed Release Tablets
Dosage Form/Strengths	Delayed Release Tablets / 20 mg
Route of Administration	Oral
Indication	Treatment of frequent heartburn (occurring two or more days a week)
Submission Date	06/02/2021
Goal date	10/02/2021
Primary Reviewer	Min Sung Suh, Ph.D.
Secondary Reviewer	Kimberly Raines, Ph.D.
Recommendation	ADEQUATE
<u>EXECUTIVE SUMMARY</u>	
<p>Background/submission:</p> <p>Omeprazole Delayed Release (DR) Tablets, 20 mg (NDA 22032) was approved on December 04, 2007 for over the counter (OTC) use. It is indicated for treatment of frequent heartburn. The Applicant, Dexcel Pharma Technologies Ltd, submitted a Prior Approval Supplement (PAS) to seek approval of the addition of a cool mint flavored formulation to the approved unflavored and wildberry mint flavored product (approved under Supplement-24). The proposed formulation (cool mint flavor) is consisted of the same tablet core as the approved formulations, and it differs from the wildberry mint formulation in color (blue) and flavor (b) (4)</p> <p>The Applicant stated that the proposed change is Level 3 as per SUPAC-MR, 1997, III.C, and that a waiver of in vivo equivalence study can be granted under 21 CFR 320.22 (d)(4). However, in the initial submission, no bioequivalence</p>	

documentation (a biowaiver request form) was included in this supplement or was any in vivo study data submitted to support the proposed change. An information request (IR) was sent to the Applicant for the biowaiver documentation. In the response to the IR dated 08/19/2021, the Applicant provided a biowaiver form to support the change¹. Multipoint dissolution data at different stages (b) (4) have been provided to support the proposed formulation.

Biopharmaceutics Assessment:

It is noted when the applicant proposed the addition of the wildberry mint flavor in Supplement-24 a bioequivalence (BE) study and comparative dissolution profile data was submitted to support the proposed change. But the BE study was not considered necessary to support the addition of flavor and replacement of color mixture. The BE study was therefore not reviewed (please refer to ONDQA Biopharmaceutics review by Dr. Tien-Mien Chen July 18, 2014). Therefore, the biopharmaceutics assessment of Supplement-52 will focus on comparative in vitro dissolution.

Based on the formulation comparison data, the proposed formulation (cool mint flavor) is similar to the approved product (wildberry mint flavor) except for differences in color and flavor that are unlikely to have impact on the bioavailability as shown in Table 1. The changes in w/w percentage are less than 5% of total formulation.

Table1. Side-by-side comparison of cool mint and wildberry mint formulation

Component	Approved Wildberry Mint flavor formulation Unit (mg/tab)	Proposed Cool Mint flavor formulation Unit (mg/tab)
(b) (4)		
Omeprazole USP	20.00	20.00
Lactose Monohydrate		(b) (4)
Sodium Starch Glycolate		

¹ \\CDSESUB1\evsprod\nda022032\0097\m1\us\112-other-correspondence\request-waiver-in-vivo-bioavailability-studies\biowaiver-request.pdf

Sodium Stearate	(b) (4)	
Sodium Stearyl Fumarate		
(b) (4)		
Hypromellose Acetate Succinate		
Talc		
Triethyl Citrate		
Monoethanolamine		
Sodium Lauryl Sulfate		
(b) (4)		
(b) (4)		
Menthol		
Sucralose		
Carnauba Wax		
Total		

Comparative dissolution studies at four time points (135, 140, 145, and 150 minutes) were investigated at different manufacturing stages to demonstrate *in vitro* dissolution similarity between the proposed (cool mint flavor) and approved (wildberry mint flavor) products. Gastric resistance dissolution was also assessed under the approved dissolution conditions (Table 2).

Table 2. Approved dissolution method and acceptance criteria

Apparatus	Speed	Medium / Temperature	Acceptance criteria	
			Gastric resistance	Dissolution
USP 2 (paddles)	100 rpm	0.1N HCl (after 2 hours, add 250 mL of 0.2 M Na ₃ PO ₄ buffer / 37°C	NLT (b) (4)	NLT (b) (4)(Q) in 30 min (after 150 min)

The dissolution profiles of the proposed and approved formulations (b) (4) are statistically comparable based on the provided MSD analysis, and comply with the approved dissolution criterion of NLT (b) (4) in 30 min (see Appendix I). It is noted that no similarity factor (f_2 value) was provided since the dissolution variability at 130 and 135 min is high (see Appendix I). The gastric resistance results also meet the criterion of NLT (b) (4).

Based on the assessment of the provided information and data, *in vitro* dissolution data support that the proposed changes in color and flavor unlikely have impact on dissolution and bioavailability. Thus, it is considered as the proposed formulation is equivalent to the approved wildberry mint flavored.

Recommendation:

The NDA-022032-SUPPL-52 is recommended for approval from a Biopharmaceutics perspective.

Appendix I

1. Comparative dissolution profiles of cool mint flavored (BY090121) and wildberry mint (BY150813) formulations

a.

Time (min)	(b) (4)	
	Dissolution (%)	
	Proposed Cool mint flavored product	Approved Wildberry Mint flavored product
	Pivotal batch BY090121 ¹	Pivotal BE batch BY150813 ³
120	(b) (4)	
130	(b) (4)	
135	(b) (4)	
140	(b) (4)	
145	(b) (4)	
150	(b) (4)	

b.

(b) (4)

Time (min)	(b) (4)	
	Dissolution (%)	
	Proposed Cool mint flavored product	Approved Wildberry Mint flavored product
	Pivotal batch BY090121 ¹⁵	Pivotal BE batch BY150813 ¹⁷
120	(b) (4)	
130		
135		
140		
145		
150		

(b) (4)

c. (b) (4)

Time (min)	(b) (4) Dissolution (%)	
	Proposed Cool mint flavored product	Approved Wildberry Mint flavored product
	Pivotal batch BY090121 ²⁹	Pivotal BE batch BY150813 ³¹
120	(b) (4)	
130		
135		
140		
145		
150		

(b) (4)

d. Dissolution comparison at different stages



Min Sung
Suh

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Kimberly
Raines

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Date: 9/09/2021 11:51:56AM
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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

PHARMACOLOGY/TOXICOLOGY REVIEW(S)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number: 22032 Prior Approval Supplement (PAS) 052
Supporting document/s: SD 190; SD 195
Applicant's letter date: 6/2/21; 8/24/21
CDER stamp date: 6/2/21; 8/24/21
Product: Omeprazole delayed release tablet
Indication: Acid reducer, frequent heartburn reliever
Applicant: Dexcel Pharma Technologies (Dexcel)
Review Office: Office of Nonprescription Drugs (ONPD)
Review Division: Division of Nonprescription Drugs 1 (DNPD-1)
Reviewer: Chibueze A. Ihunnah, PhD, DABT
Supervisor/Team Leader: Jane J. Sohn, PhD
Division Director: Nushin Todd, MD, PhD
Project Manager: Phong Pham, PharmD, MBA

Except as specifically identified, all data and information discussed below and necessary for approval of NDA 22032-S052 are owned by Dexcel Pharma Technologies or are data for which Dexcel Pharma Technologies has obtained a written right of reference. Any information or data necessary for approval of NDA 22032-S052 that Dexcel Pharma Technologies does not own or have a written right to reference constitutes one of the following: (1) published literature, or (2) a prior FDA finding of safety or effectiveness for a listed drug, as reflected in the drug's approved labeling. Any data or information described or referenced below from reviews or publicly available summaries of a previously approved application is for descriptive purposes only and is not relied upon for approval of NDA 22032-S052.

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No table of figures entries found.

1 Executive Summary

1.1 Introduction

The Sponsor, Dexcel Pharma Technologies (Dexcel), submitted the prior approval supplement (PAS) for omeprazole delayed-release tablets (20 mg). The PAS proposed a new cool mint flavored, blue color coated drug product. No changes have been proposed for the concentration of the active pharmaceutical ingredient (API), dosing regimen, route of exposure, indication, or clinical population.

The goal of this review is to evaluate the proposed conditions of use for the new inactive ingredients which have been proposed for the cool mint formulation.

1.2 Brief Discussion of Nonclinical Findings

There are no nonclinical concerns regarding the proposed excipients. The pharmacology/toxicology (PT) reviewer performed a toxicological safety assessment for each proposed excipient (except the (b) (4) additives) considering the maximum daily exposure (MDE), clinical population, duration of dosing, route of exposure, and indication. The PT reviewer relied upon publicly available toxicological information from literature and databases, as well as internal FDA databases.

Refer to the CMC review for an assessment of the approvability of the proposed color additives.

1.3 Recommendations

1.3.1 Approvability

Approvable from the nonclinical perspective.

1.3.2 Additional Non Clinical Recommendations

None.

1.3.3 Labeling

Not applicable.

2 Drug Information

2.1 Drug

CAS Registry Number
73590-58-6

Generic Name
Omeprazole

Code Name
Not applicable

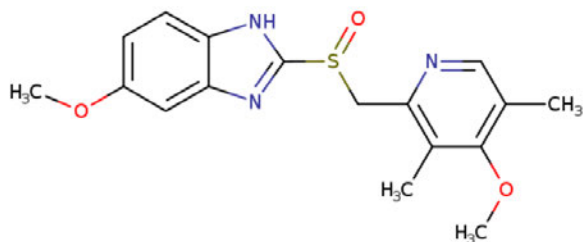
Chemical Name

1H-Benzimidazole, 5-methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl)-

Molecular Formula/Molecular Weight

C₁₇H₁₉N₃O₃S / 345.4211

Structure or Biochemical Description



Pharmacologic Class

Proton Pump Inhibitor

2.2 Relevant INDs, NDAs, BLAs and DMFs

None.

2.3 Drug Formulation

The drug formulation is illustrated in the tables below (excerpted from the application).

Table 1. Unit dose comparison for the approved and proposed omeprazole delayed-release tablets

Name of Constituent	Quantity per Tablet [mg]			Function of constituent	Grade
	Unflavored	Currently approved Wildberry Mint Flavored	Proposed Cool Mint Flavored		
(b) (4)					
Omeprazole	20.00	20.00	20.00	Drug substance	USP
Lactose Monohydrate	(b) (4)			(b) (4)	NF
Sodium Starch Glycolate				NF	
Sodium Stearate				NF	
Sodium Stearyl Fumarate				NF	
(b) (4)					
Hypromellose Acetate Succinate				NF	
Talc				USP	
Triethyl Citrate				NF	
Monoethanolamine				NF	
Sodium Lauryl Sulfate				NF	
(b) (4)				(b) (4)	
Menthol	(b) (4)				NF
(b) (4)					(b) (4)
Sucralose					NF
Carnauba wax					NF
Total weight	285.00	307.00	307.00		



2.4 Comments on Novel Excipients

There are no novel excipients which are proposed for the cool mint flavor drug product. (See the Integrated Summary.)

2.5 Comments on Impurities/Degradants of Concern

None. There are no proposed changes to the manufacturing elements of the drug substance. Further, no new impurities have been identified by the CMC reviewer¹.

2.6 Proposed Clinical Population and Dosing Regimen

No changes have been proposed for the clinical population or dosing regimen.

The approved omeprazole presentations (flavored and unflavored) are indicated for adults aged 18 years and older. The approved dose is once daily oral administration for 14 days. The 14-day regimen may be repeated every 4 months².

2.7 Regulatory Background

NDA 22032 for omeprazole delayed release tablets (20 mg), was originally approved on December 4, 2007. The Sponsor, Dexcel Pharma Technologies (Dexcel), submitted the application for the unflavored delayed release drug product. The subsequent wildberry mint drug product (omeprazole 20 mg) was also submitted by Dexcel and was approved in 2014.

3 Studies Submitted

3.1 Studies Reviewed

None.

¹ Email correspondence with CMC primary reviewer, Ping Jiang-Baucom, PhD 9/2/21

² PRPLL current approved labeling for omeprazole, delayed release tablet (NDA 22032)

3.2 Studies Not Reviewed

Not applicable because no new studies were submitted.

3.3 Previous Reviews Referenced

None.

4 Integrated Summary and Safety Evaluation

The Sponsor, Dexcel Pharma Technologies (Dexcel), submitted the prior approval supplement (PAS) on June 2, 2021 for Omeprazole delayed-release tablets (20 mg). The PAS proposed a new cool mint flavored, blue colored drug product. New inactive ingredients have been proposed for the cool mint formulation, but no changes have been proposed for the concentration of the API, dosing regimen, or clinical population.

Regarding the inactive ingredients, the proposed cool mint drug product contains a (b) (4) of menthol (b) (4) than the approved wildberry mint drug product. (b) (4)

(b) (4) The proposed cool mint drug product also contains (b) (4) hypromellose, titanium dioxide, triacetin, FD&C Blue #1/Brilliant Blue FCF aluminum lake (b) (4)

(b) (4) The pharmacology/toxicology (PT) reviewer performed a toxicological safety assessment for each new proposed component except the (b) (4) additives titanium dioxide, and FD&C Blue #1/Brilliant Blue FCF aluminum lake colors. Refer to the CMC review regarding the proposed use and approvability of the (b) (4) additives³.

After a review of the individual components (except the (b) (4) additives), it appears that the conditions of use for the proposed components which comprise the cool mint drug product are acceptable from the nonclinical perspective. Refer to the section below for the toxicological safety assessment for each individual proposed component.

Proposed excipients

The following excipients were proposed by the Sponsor and are not present in the approved unflavored or wildberry flavored products, or are proposed at an MDE that exceeds the level in the approved unflavored or wildberry flavored products.

Menthol (b) (4)

Menthol (b) (4) For clarification and completeness, ONPD sent an information request (IR) to the Sponsor for clarification of the identity of menthol (b) (4) The

³ Email correspondence with CMC primary reviewer, Ping Jiang-Baucom, PhD 9/2/21

⁴ Handbook of Pharmaceutical Excipients, 6th edition 2009

Sponsor responded on August 24, 2021 and provided sufficient information to confirm the identity of menthol (b) (4). Further, the United States Pharmacopeia (USP) also published a monograph detailing supportive specification information for menthol (b) (4).

The Sponsor proposes (b) (4) of menthol (b) (4) per tablet. The drug product is proposed for once daily use, therefore the MDE is (b) (4) of menthol (b) (4).

Note, the amount of menthol (b) (4) that is in the approved wildberry mint flavor formulation is (b) (4). Further, there are several approved NDA/ANDA drug products with higher maximum daily exposures (MDE's) than the proposed cool mint drug product with the same conditions of use (duration, dose, clinical population).

There is no safety concern regarding the use of menthol (b) (4) for the proposed conditions of use.

Hypromellose

(b) (4)

Hypromellose (hydroxypropyl methyl cellulose) is a form of a O-methylated and O-hydroxypropylated cellulose. In pharmaceutical products, hypromellose is primarily used as a tablet binder, embedding matrix, controlled release agent, dissolution enhancer, emulsifying agent or a film coating⁶.

(b) (4)

There is no safety concern regarding the use of hypromellose for the proposed conditions of use.

Titanium Dioxide

(b) (4)

Titanium dioxide is a white, amorphous, odorless, and tasteless non-hygroscopic powder. It is used widely in foods, cosmetics and pharmaceuticals. In pharmaceutical formulations, titanium dioxide is used as a white pigment in film-coating suspensions, dermatological preparations, and also sunscreens⁷.

⁵ USP monograph menthol, briefing 2018

⁶ Handbook of Pharmaceutical Excipients, 6th edition 2009

⁷ Handbook of Pharmaceutical Excipients, 6th edition 2009

Refer to the CMC review regarding compliance of the proposed conditions of use (b) (4) to the CFR.

Triacetin

(b) (4)

Triacetin is a colorless, viscous liquid. In pharmaceutical products, it is primarily used as a polymeric capsule coating. It is also used in cosmetic products and foods as a solvent⁸.

(b) (4)

There is no safety concern regarding the use of triacetin for the proposed conditions of use.

FD&C Blue #1/Brilliant Blue FCF aluminum lake

(b) (4)

FD&C Blue #1/Brilliant Blue FCF aluminum lake (b) (4) is a color which the Sponsor proposes to include in the formulation at a level of (b) (4) per tablet (Table 2). Refer to the CMC review regarding compliance of the proposed conditions of use (b) (4) to the CFR⁹.

(b) (4)

⁸ Handbook of Pharmaceutical Excipients, 6th edition 2009

⁹ Email correspondence with CMC primary reviewer, Ping Jiang-Baucom, PhD 9/2/21

¹⁰ Email correspondence with CMC primary reviewer, Ping Jiang-Baucom, PhD 9/2/21

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/s/

CHIBUEZE A IHUNNAH
09/02/2021 11:12:12 AM

JANE J SOHN
09/02/2021 11:38:14 AM
I concur.

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022032Orig1s052

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

Pham, Phong

From: Pham, Phong
Sent: Friday, August 20, 2021 3:08 PM
To: Kneifel, Amy
Cc: Kim, Cynthia
Subject: Information Request | NDA 022032-052 omeprazole delayed release tablet, 20 mg.

Amy,

Kindly confirm receipt of this communication.

We refer to your prior approval supplement (PAS) submitted under NDA 022032-S052 and received on June 2, 2021 is currently under review. We have the following information request:

1. Menthol (b) (4)
 - a. (b) (4)

Submit the requested information as an official response to the NDA in eCTD format over the Gateway by 5 PM EST on August 27, 2021.

Phong (On behalf of Cindy Kim, PharmD, Regulatory Project Manager)

Phong Pham, PharmD, MBA
Regulatory Project Manager

Division of Nonprescription Drugs I
Division of Regulatory Operations for Nonprescription Drugs
Office of Regulatory Operations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
E | Phong.Pham@fda.hhs.gov



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/s/

PHONG T PHAM
08/20/2021 03:17:03 PM

Pham, Phong

From: Tran, Suong T
Sent: Wednesday, July 21, 2021 12:24 PM
To: Pham, Phong
Cc: Stewart, Sherry
Subject: RE: Finalized - NDA 22032 General Consult Request(FRM-CONSULT-01)

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Phong-

This botanical consult request for a pharmacognosy review of the excipient Menthol (b) (4) NF is not necessary because:

- This excipient is compendial,
- This excipient is already part of the currently approved formulation (b) (4)
- The request for general information (“Scientific name of the plant species, Synonyms, Subspecific rank (subspecies, variety, and form) and cultivars, if applicable, Family name, Botanical parts used, Common or usual names in English”) should be sent to the NDA applicant, and
- The request for “Quality control related to current manufacturing practices” should be sent to the Quality/CMC team reviewing this supplement 52.

Please withdraw or close out the consult request in DARRTS. If you decide that a consult request is necessary, please provide a clarification on the requested pharmacognosy review of this compendial excipient that is already part of the currently approved formulation and please provide specific documents that my reviewer would evaluate.

Thanks,

Su

Suong Tran, PhD
Branch Chief
DNDAPI/ONDP/OPQ/CDER

From: Wu, Charles (CDER) <Charles.Wu@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 11:48 AM
To: Pham, Phong <Phong.Pham@fda.hhs.gov>; Tran, Suong T <Suong.Tran@fda.hhs.gov>
Cc: Stewart, Sherry <Sherry.Stewart@fda.hhs.gov>; Taylor, Cassandra <Cassandra.Taylor@fda.hhs.gov>
Subject: RE: Finalized - NDA 22032 General Consult Request(FRM-CONSULT-01)

Hi, Phong:

I have forwarded the botanical consult to Dr Tran’s team to handle it given BRT is short staffed at the moment.

Thanks,
Charles

From: Pham, Phong <Phong.Pham@fda.hhs.gov>
Sent: Thursday, July 15, 2021 8:43 AM
To: Taylor, Cassandra <Cassandra.Taylor@fda.hhs.gov>; Wu, Charles (CDER) <Charles.Wu@fda.hhs.gov>
Cc: Stewart, Sherry <Sherry.Stewart@fda.hhs.gov>
Subject: FW: Finalized - NDA 22032 General Consult Request(FRM-CONSULT-01)

Hello friends,

We appreciate your help and expertise on this application. I filed this consult under OPQ since I didn't specifically see your division listed. Let me know if anything needs to be adjusted. Welcome aboard. 😊

- Phong

From: ora_ias@fdslv96017.fda.gov <ora_ias@fdslv96017.fda.gov>

Sent: Thursday, July 15, 2021 8:28 AM

To: Wu, Charles (CDER) <Charles.Wu@fda.hhs.gov>; Pham, Phong <Phong.Pham@fda.hhs.gov>; Taylor, Cassandra <Cassandra.Taylor@fda.hhs.gov>; Kim, Cynthia <Cynthia.Kim@fda.hhs.gov>; Ihunnah, Chibueze <Chibueze.Ihunnah@fda.hhs.gov>

Subject: Finalized - NDA 22032 General Consult Request(FRM-CONSULT-01)



(b) (4)

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/s/

PHONG T PHAM
08/10/2021 10:15:01 AM

PHARMACOLOGY/TOXICOLOGY FILING CHECKLIST FOR NDA/BLA or Supplement

NDA Number: 22032

Applicant: Dexcel Pharma
Technologies

Stamp Date: June 2, 2021

Drug Name: Omeprazole
Delayed Release Tablets

NDA Type: PAS 052

On **initial** overview of the NDA/BLA application for filing:

	Content Parameter	Yes	No	Comment
1	Is the pharmacology/toxicology section organized in accord with current regulations and guidelines for format and content in a manner to allow substantive review to begin?			Not applicable, there are no nonclinical studies submitted.
2	Is the pharmacology/toxicology section indexed and paginated in a manner allowing substantive review to begin?			Not applicable, there are no nonclinical studies submitted.
3	Is the pharmacology/toxicology section legible so that substantive review can begin?			Not applicable, there are no nonclinical studies submitted.
4	Are all required and requested IND studies (in accord with 505 (b)(1) and (b)(2) including referenced literature) completed and submitted (carcinogenicity, mutagenicity, teratogenicity, effects on fertility, juvenile studies, acute and repeat dose adult animal studies, animal ADME studies, safety pharmacology, etc)?			Not applicable, there are no nonclinical studies submitted.
5	If the formulation to be marketed is different from the formulation used in the toxicology studies, have studies by the appropriate route been conducted with appropriate formulations? (For other than the oral route, some studies may be by routes different from the clinical route intentionally and by desire of the FDA).			Not applicable, there are no nonclinical studies submitted.
6	Does the route of administration used in the animal studies appear to be the same as the intended human exposure route? If not, has the applicant <u>submitted</u> a rationale to justify the alternative route?			Not applicable, there are no nonclinical studies submitted.
7	Has the applicant <u>submitted</u> a statement(s) that all of the pivotal pharm/tox studies have been performed in accordance with the GLP regulations (21 CFR 58) <u>or</u> an explanation for any significant deviations?			Not applicable, there are no nonclinical studies submitted.
8	Has the applicant submitted all special studies/data requested by the Division during pre-submission discussions?			Not applicable, there are no nonclinical studies submitted.

PHARMACOLOGY/TOXICOLOGY FILING CHECKLIST FOR NDA/BLA or Supplement

	Content Parameter	Yes	No	Comment
9	Are the proposed labeling sections relative to pharmacology/toxicology appropriate (including human dose multiples expressed in either mg/m ² or comparative serum/plasma levels) and in accordance with 201.57?			Not applicable, there are no nonclinical studies submitted.
10	Have any impurity, degradant, extractable/leachable, etc. issues been addressed? (New toxicity studies may not be needed.)		x	(b) (4) The CMC reviewer has not reported any additional new impurities or degradants, however, the potential for new impurities or degradants will be a review issue.
11	If this NDA/BLA is to support a Rx to OTC switch, have all relevant studies been submitted?			Not applicable.
12	If the applicant is entirely or in part supporting the safety of their product by relying on nonclinical information for which they do not have the right to the underlying data (i.e., a 505(b)(2) application referring to a previous finding of the agency and/or literature), have they provided a scientific bridge or rationale to support that reliance? If so, what type of bridge or rationale was provided (e.g., nonclinical, clinical PK, other)?		x	The Sponsor proposes a new cool mint flavor formulation. No information was submitted to support the new formulation. (b) (4)

IS THE PHARMACOLOGY/TOXICOLOGY SECTION OF THE APPLICATION FILEABLE? ____ Yes ____

If the NDA/BLA is not fileable from the pharmacology/toxicology perspective, state the reasons and provide comments to be sent to the Applicant.

Please identify and list any potential review issues to be forwarded to the Applicant for the 74-day letter.

The Sponsor should clarify the chemical composition of menthol (b) (4)

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/s/

CHIBUEZE A IHUNNAH
07/29/2021 10:58:40 AM

JANE J SOHN
07/29/2021 11:34:56 AM
I concur.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Sent: 07/21/2021 01:32:06 PM

To: AMY.KNEIFEL@ICONPLC.COM

CC:

BCC:

Subject: INFORMATION REQUEST NDA 22032/S-052

Please see attached Information Request.

Thanks,

Laya

Please find the attached documents below:

[NDA-022032-SUPPL-52_Send IR_Pending \(1\).pdf](#)

APPEARS THIS WAY ON ORIGINAL





NDA 022032/S-052

INFORMATION REQUEST

Dexcel Pharma Technologies Ltd
c/o Icon Clinical Research LLC
Attention: Amy Kneifel
79 Tw Alexander Dr.
4401 Research Commons Bldg., Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your supplemental New Drug Application (sNDA) dated June 02, 2021, received June 02, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Delayed Release Tablets, 20mg.

We are reviewing the Biopharmaceutics section of your submission and have the following comments and information requests. We request a prompt written response by July 23, 2021 in order to continue our evaluation of your supplemental NDA.

Comments and information requests:

A. Biopharmaceutics

1. As per SUPAC-MR Guidance, bioequivalence documentation is required to support your PAS submission. As you do not submit any in vivo BE data to support the proposed change, please submit a biowaiver form under Module 1.12.15 "Request for waiver of in vivo bioavailability studies" per 21 CFR 320.22. (d)(4) with supportive information.

If you have any questions, please contact Laya Keyvan, Regulatory Program Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Laya Keyvan, MS, MBA
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



Laya
Keyvan

Digitally signed by Laya Keyvan

Date: 7/21/2021 01:30:53PM

GUID: 530f6b9a0000831d04a85a3c1d7c9538

Office of Nonprescription Drugs (ONPD) Pharmacology/Toxicology (PT) Requestor: Chibueze Ihunnah, PhD, DABT	Botanical Consult Request Form
--	---------------------------------------

Date:7/14/2021	Desired Completion Date:7/30/2021
----------------	-----------------------------------

Reason for Request

<input checked="" type="checkbox"/> Please provide the following general information for menthol (b) (4) <ul style="list-style-type: none"> • Scientific name of the plant species • Synonyms • Subspecific rank (subspecies, variety, and form) and cultivars, if applicable • Family name • Botanical parts used • Common or usual names in English 	<input checked="" type="checkbox"/> Quality control related to current manufacturing practices
---	--

Supporting Information for Consult
(provide electronic copy of literature or other reference if possible as attachment)

I. Compound information


Compound	CASRN (if applicable)	UNII (optional)	Species Name

II. Detailed description of reason for consult

A sponsor has proposed to use a compound, which they call "menthol (b) (4) as a flavor in an oral product. The composition of menthol (b) (4) is unclear. (b) (4)

(b) (4)

III. Pertinent review information/references (e.g., literature, internal information, etc). Provide citations, or list of attachments, as appropriate.

The drug product formulation is provided in the pdf below for reference. Menthol
^{(b) (4)} is highlighted in yellow.



description-and-com
position-2.pdf

APPEARS THIS WAY ON ORIGINAL

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/s/

PHONG T PHAM
07/15/2021 08:27:59 AM



NDA 022032/S-052

INFORMATION REQUEST

Dexcel Pharma Technologies Limited
c/o ICON Clinical Research LLC (Authorized Agent)
Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Dr.
4401 Research Commons Bldg., Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) 022032/S-052 dated and received June 2, 2021, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for omeprazole delayed release tablets, 20 mg.

We are reviewing your submission and have the following comments and information request. We request a prompt written response in order to continue our evaluation of your supplemental application.

All labeling submitted to S-052:

1. Consider removing the boldface type on “Frequent” in the statement “Treats Frequent Heartburn!” on the principal display panel (PDP) to ensure that the word “Frequent” does not overshadow the statement “Treats Frequent Heartburn!”
2. We recommend applying boldface type to the number of treatment courses statement below the declaration of net quantity (e.g., “One 14-day course of treatment”).
3. We recommend increasing the prominence of the nonprescription proton pump inhibitor class labeling statement “May take 1 to 4 days for full effect” to be as large as the statement “One 14-day course of treatment” in the lower third portion of the PDP. We also recommend using boldface type.
4. Consider using a different font color on the promotional statements displayed in (b) (4) text on a light blue background (e.g., “Bonus Pack! 14 Free,” “Triple Pack Three 14-day courses of treatment”, etc.) to improve the contrast and readability.

2-count outer carton labeling:

5. Apply boldface type to the statement “First 2 doses of 14-day course of treatment” to provide clarity to consumers on how the sample doses fit into the set treatment course for the drug product.
6. Add the nonprescription proton pump inhibitor class labeling statement “May take 1 to 4 days for full effect” in boldface type to the 2-count outer carton labeling.

2-count outer carton label:

7. Submit the 2-count immediate container label because it appears to be missing from the June 2, 2021 submission.

14-count inner carton:

8.



9. Apply boldface type to the entire declaration of net quantity of contents statement, including “TABLETS”, per 21 201.62(c).
10. Apply boldface type to the entire statement of identity including, “Delayed Release Tablets 20 mg” on the PDP, per 21 CFR 201.61(c).

42-count outer carton labeling with a Value Pack statement:

11. Spell out “three” in the statement “Value Pack! 3 -14 Tablet Cartons” to avoid confusion with the quantity of product contents. As currently written, it can be read to express that this outer carton contains between three to fourteen tablet cartons, which would be inaccurate. The statement “Value Pack! Three -14 Tablet Cartons” will better clarify the outer carton contents.

Kindly provide an official response in eCTD format over the gateway by 5 p.m. Eastern Standard Time on July 14, 2021.

If you have questions, call Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

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/s/

NUSHIN F TODD
07/01/2021 10:05:48 AM

Filing Review for Omeprazole Delayed Release Tablets, 20 mg

SUBMISSION DATES: June 2, 2021

NDA/SUBMISSION TYPE: NDA 022-032/S-052 (PAS)

ACTIVE INGREDIENT: Omeprazole, 20 mg

DOSAGE FORM: Delayed Release Tablets

APPLICANT: Dexcel Pharma Technologies Ltd.
US Agent: ICON Clinical Research, LLC
Amy Kneifel, Director of Regulatory Affairs
Phone: 919-294-2241; Email: amy.kneifel@iconplc.com

REVIEWER: Lori Parsons, PhD, DNPD 1/ONPD

ASSOC DIRECTOR: Kevin Lorick, PhD, DNPD 1/ONPD

Supplement 052 is a CMC + labeling Prior Approval Supplement (PAS) that proposes an additional of mint flavored formulation (termed cool mint in the labeling) and 42 new labeling components (36 immediate container/outer carton labeling; and 6 Instantly Redeemable Coupons). The applicant submitted CMC and pharmacology toxicology data to support this supplement.

Submitted Labeling	Representative of Following SKUs
Cool Mint Flavored Tablets	
14-count immediate container (blister)	N/A
2-count physician sample outer carton (blister)	N/A
14-count inner carton	N/A
14-count outer carton (blister)	N/A
14-count outer carton with “FDA Approved” statement (blister)	N/A
28-count outer carton (blister)	N/A
28-count outer carton with “14 Free” statement (blister)	N/A
28-count outer carton with “Bonus! 14 Free” statement (blister)	N/A
28-count outer carton with “Bonus Pack! 14 Free” statement (blister)	N/A
28-count outer carton with “FDA Approved” statement (blister)	N/A
42-count outer carton (blister)	N/A
42-count outer carton with “14 Free” statement (blister)	N/A
42-count outer carton with “3 PACK Three 14-day courses of treatment” statement (blister)	N/A
42-count outer carton with “28 + 14 FREE” statement (blister)	N/A
42-count outer carton with “Bonus! 14 Free” statement (blister)	N/A
42-count outer carton with “Bonus Pack! 14 Free” statement (blister)	N/A
42-count outer carton with “FDA Approved” statement (blister)	N/A
42-count outer carton with “Triple Pack Three 14-day courses of treatment” statement (blister)	N/A
42-count outer carton with “Value Pack 3- 14-day courses of treatment” statement (blister)	N/A

Submitted Labeling	Representative of Following SKUs
Cool Mint Flavored Tablets	
14-count immediate container (bottle)	N/A
14-count outer carton (bottle)	N/A
14-count outer carton with “FDA Approved” statement (bottle)	N/A
28-count outer carton (bottle)	N/A
28-count outer carton with “14 Free” statement (bottle)	N/A
28-count outer carton with “Bonus! 14 Free” statement (bottle)	N/A
28-count outer carton with “Bonus Pack! 14 Free” statement (bottle)	N/A
28-count outer carton with “FDA Approved” statement (bottle)	N/A
42-count outer carton (bottle)	N/A
42-count outer carton with “14 Free” statement (bottle)	N/A
42-count outer carton with “3 PACK Three 14-day courses of treatment” statement (bottle)	N/A
42-count outer carton with “28 + 14 FREE” statement (bottle)	N/A
42-count outer carton with “Bonus! 14 Free” statement (bottle)	N/A
42-count outer carton with “Bonus Pack! 14 Free” statement (bottle)	N/A
42-count outer carton with “FDA Approved” statement (bottle)	N/A
42-count outer carton with “Triple Pack Three 14-day courses of treatment” statement (bottle)	N/A
42-count outer carton with “Value Pack 3- 14-day courses of treatment” statement (bottle)	N/A
14-count IRC (blister)	N/A
14-count IRC (bottle)	N/A
28-count IRC (blister)	N/A
28-count IRC (blister)	N/A
42-count IRC (bottle)	N/A
42-count IRC (bottle)	N/A

Issues	Yes/No	Comments
Is the supplement correctly assigned as a PA, CBE0, CBE30?	Yes	CMC + Labeling PAS
Are the outer container and immediate container labels, and consumer information leaflet and other labeling included for all submitted SKUs?	No	2-count immediate container label is missing. IR proposed to request this label submission to S-052 for review.
If representative labeling is submitted, does the submitted labeling represent only SKUs of different count sizes (same flavor and dosage form)?	N/A	
Is distributor labeling included?	No	
Does the submission include the annotated specifications for the Drug Facts label?	Yes	
Is Drug Facts title and Active ingredient/Purpose section of Drug Facts label visible at time of purchase?	Yes	
Do any of the labels include "prescription strength" or similar statements?	No	
Do any of the labels include "#1 doctor recommended" or similar endorsement statements?	No	
Do any labels include text in a language other than English?	No	
Is a new trade name being proposed? If multiple trade names, is the primary or preferred trade name identified?	No	
Does a medical officer need to review any clinical issues?	No	
If SLR, should OPQ also review?	Yes	S-052 submission includes CMC and pharmacology toxicology data.

Information Request:

Filing review identified labeling improvement considerations to better support consumer messaging around qualities of this drug product. An information request is recommended. The information request content is below.

Please refer to your supplemental new drug application sNDA 022032/052/Omeprazole Delayed-Release Tablets, dated and received June 2, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Delayed-Release Tablets, 20 mg.

We have the following information request and advice:

All labeling submitted to S-052:

1. Consider removing the boldface type on “Frequent” in the statement “Treats Frequent Heartburn!” on the PDP to ensure that the word “Frequent” does not overshadow the statement “Treats Frequent Heartburn!”
2. We recommend applying boldface type to the number of treatment courses statement below the declaration of net quantity (e.g., “One 14-day course of treatment).
3. We recommend increasing the prominence of the nonprescription proton pump inhibitor class labeling statement “May take 1 to 4 days for full effect” to be as large as the statement “One 14-day course of treatment” in the lower third portion of the PDP. We recommend using boldface type.
4. Consider using a different font color on the promotional statements displayed in (b) (4) text on a light blue background (e.g., Bonus Pack! 14 Free, Triple Pack Three 14-day courses of treatment, etc.) because it may be difficult to read.

2-count outer carton labeling:

5. Apply bold face type to the statement “First 2 doses of 14-day course of treatment” to provide clarity to consumers on how the sample doses fit into the set treatment course for the drug product.
6. Add the nonprescription proton pump inhibitor class labeling statement “May take 1 to 4 days for full effect” in boldface type to the 2-count outer carton labeling.

2-count outer carton label:

7. Submit the 2-count immediate container label because it appears to be missing from the June 2, 2021 submission.

14-count inner carton:

8. (b) (4)
9. Apply boldface type to the entire declaration of net quantity of contents statement, including “TABLETS”, per 21 201.62(c).
10. Apply boldface type to the entire statement of identity including, “Delayed Release Tablets 20 mg” on the PDP, per 21 CFR 201.61(c).

42-count outer carton labeling with a Value Pack statement:

11. Spell out “three” in the statement “Value Pack! 3 -14 Tablet Cartons” to avoid confusion with the quantity of product contents. As currently written, it can be read to express that this outer carton contains between three to fourteen tablet cartons, which would be inaccurate. The statement “Value Pack! Three -14 Tablet Cartons” will better clarify the outer carton contents.

Reviewer’s Comment:

Supplement 046 is fileable from a labeling perspective.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORI N PARSONS
06/29/2021 04:19:19 PM

KEVIN L LORICK
07/01/2021 02:04:38 PM
I concur with the review. There are no issues to prevent filing.



NDA 022032/S-052

**ACKNOWLEDGMENT --
PRIOR APPROVAL SUPPLEMENT**

Dexcel Pharma Technologies Limited
c/o ICON Clinical Research LLC (Authorized Agent)
Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Dr.
4401 Research Commons Bldg., Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

We have received your supplemental new drug application (sNDA) submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 022032
SUPPLEMENT NUMBER: 052
PRODUCT NAME: omeprazole delayed release tablets, 20 mg
DATE OF SUBMISSION: JUNE 2, 2021
DATE OF RECEIPT: JUNE 2, 2021

This supplemental application proposes the following change for omeprazole delayed release tablets: addition of a cool mint flavored formulation.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on AUGUST 1, 2021, in accordance with 21 CFR 314.101(a).

If the application is filed, the user fee goal date will be October 2, 2021.

If you have questions, call me at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

Phong Pham, PharmD, MBA
Regulatory Project Manager
Division of Nonprescription Drugs I
Division of Regulatory Operations for Nonprescription Drugs
Office of Regulatory Operations
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PHONG T PHAM
06/23/2021 03:55:58 PM

Initial Quality Assessment - OLDP Division of Post-Marketing Activities I

NDA: 22032	Applicant: ICON Clinical Research, LLC	Product: Omeprazole Delayed Release Tablets
Supplement: 52		
Clinical Division: CDER/ODEIV/DNDP		
Managed by: OND <input checked="" type="checkbox"/> <i>Efficacy</i> <input type="checkbox"/> <i>Labeling</i> <input checked="" type="checkbox"/>		OPQ <input type="checkbox"/>
Receipt Date: 06/02/2021		PDUFA Goal Date: 10/02/2021
Proposed changes: Addition of Cool Mint Flavored Formulation		
Complete Response: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
Submitted Category: CBE-0 <input type="checkbox"/> CBE-30 <input type="checkbox"/> PA <input checked="" type="checkbox"/>		Final Category: CBE-0 <input type="checkbox"/> CBE-30 <input type="checkbox"/> PA <input checked="" type="checkbox"/>
Expedited Review Requested: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Drug Shortage: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Group Supplements: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Other Disciplines: Facility: <input type="checkbox"/> Micro: <input type="checkbox"/> ¹ Biopharm: <input type="checkbox"/> biowaiver request is missing. need to check with biopharm for biowaiver request Pharm/tax: <input type="checkbox"/> Statistics: <input type="checkbox"/> OPF: <input type="checkbox"/> DMEPA: <input checked="" type="checkbox"/> Clin Pharm: <input type="checkbox"/> DMF: <input type="checkbox"/> CDHR/ODE <input type="checkbox"/> CDHR/OC <input type="checkbox"/> ² Formulation Change <input type="checkbox"/> Others: Clin		
Comments: <p>The formulation of the Cool Mint flavored Omeprazole Delayed Released Tablets, 20mg is quantitatively and qualitatively the same as the current wildberry mint formulation. It differs from the wildberry mint flavored formulation in color (b) (4). The cool mint flavored formulation will be included in the same NDA.</p> <p>Omeprazole cool mint Delayed Release Tablets, 20mg is identical, except for a color and flavor change, to the product which its bioavailability has been measured, and both products meet appropriate <i>in vitro</i> tests approved by the FDA.</p> <p>The firm states in the cover letter that the proposed formulation of the Cool Mint flavored Omeprazole Delayed Released Tablets is therapeutically equivalent to the current approved Omeprazole Delayed Release Tablets, 20mg, however, the biowaiver request is not submitted.</p> <p>The following are provided:</p> <ol style="list-style-type: none"> Draft labels for the proposed cool mint (Section 1.14.1) Complete Module 3 for drug product 		
QAL: Joyce Crich	Date: 06/09/2021	
Assigned Reviewer: Ping Jiang-Baucom	RBPM: Laya Keyvan	

¹Refer to the MOU between OLDP and ONDP for scenarios that require Biopharm consult.

²Notify Andre Raw and copy DD & BC and request for a Biopharm reviewer.