

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
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Push tablet through foil.
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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

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Omeprazole DR Tablets 20mg
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= No Print Area

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

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

<p>Drug Facts (continued)</p> <p>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 ■ 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</p> <p>■ If you take 1 to 4 days for full effect, some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>■ Swallow 1 tablet with a glass of water before eating in the morning</p> <p>■ Take every day for 14 days</p> <p>■ Do not take more than 1 tablet a day</p> <p>■ Do not use for more than 14 days unless directed by your doctor</p> <p>■ Swallow whole. Do not chew, crush, or suck tablets.</p> <p>Repeated 14-Day Courses (if needed)</p> <p>■ You may repeat a 14-day course every 4 months rather 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>Other Information</p> <p>■ Read the directions and warnings before use</p> <p>■ Keep the carton. It contains important information</p> <p>■ Store at 20°-25°C (68°-77°F) and protect from moisture</p> <p>Inactive Ingredients ■ Every alcohol, carmine, carnauba wax, FD&C blue #2, iron oxides black, iron oxides red, iron oxides yellow, polyethylene glycol 350, polyethylene glycol 400, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearoyl fumarate, sucrose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9260</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg</p> <p>Purpose Acid reducer</p> <p>Use ■ Treats the frequent heartburn (occurs 2 or more days a week) ■ Do not take for immediate relief of heartburn (this drug may take 1 to 4 days for full effect)</p> <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have heartburn over 3 months, this may be a sign of a more serious condition</p> <p>Be alert for lightheadedness, weakness, or dizziness chest pain or shoulder pain with shortness of breath, sweating; pain spreading to arms, neck or shoulders, or tight headaches; faint or lightheadedness, particularly with heartburn</p> <p>■ Stomach pain ■ Explained weight loss ■ Nausea or vomiting</p> <p>Ask a doctor or pharmacist before use if you are taking</p> <p>■ Warfarin, clopidogrel or clostazolide (blood-thinning medicines) ■ Prescription antifungal or antibiotic medicines</p> <p>■ Tacrolimus (immune system medicine) ■ Digoxin (heart medicine) ■ Dexamethasone (steroid medicine)</p> <p>Stop use and ask a doctor if</p> <p>■ Your heartburn continues or worsens ■ You need to take this product for more than 14 days ■ You get diarrhea ■ You get dizziness</p> <p>If pregnant or breastfeeding, ask a health professional before use:</p> <p>■ You get diarrhea ■ You need to take more than 1 course of treatment every 4 months ■ Your heartburn continues or worsens ■ You need to take this product for more than 14 days</p>
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Batch No. : 40374 00 VA
 EXP : 40374 00 VA
CODE AREA
 Safety Feature - Do not use if printed tablet blister unit separates from

NOT FOR RESALE

Made in Israel

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

Treats Frequent Heartburn!
Occurring 2 or More Days a Week

Omeprazole

delayed release tablets 20 mg acid reducer



Coated with
Wildberry Mint Flavor

SWALLOW - DO NOT CHEW

14 TABLETS

One 14-day course of treatment

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

MODIFIED FORMAT

TYPE SIZES:
 TITLE: 8 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 7 pt Helvetica Neue 77 Bold Cond Oblique (continued)
 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: 6.5 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

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

Manufactured by:
 Omeprazole Pharmaceuticals, Ltd.,
 10 Redstone Street, Johnson, 08052, USA

Made in Israel

<p>Questions or comments? 1-800-719-9260</p> <p>Inactive ingredients benzyl alcohol, camphor, carnauba wax, FD-C Blue #2, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, menthol, hypromellose, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triethyl citrate.</p> <p>Other information</p> <ul style="list-style-type: none"> ■ Read the directions and warnings before use ■ Keep the carton it contains in a cool, dry place (20°-25°C, 68°-77°F) and protect from moisture <p>Directions ■ For adults 18 years of age and older</p> <p>Warnings</p> <p>Do not use if you are allergic to omeprazole</p> <p>Use ■ Treats frequent heartburn (occurs 2 or more days a week) Omeprazole 20 mg delayed release tablets 1 to 4 days for full effect</p> <p>Purpose Acid reducer</p> <p>Active ingredient (in each tablet)</p>	<p>Drug Facts</p> <p>Warnings</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with food, 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 difficulty swallowing, 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 exertion ■ stomach 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 clozapine (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ dexamethasone (steroid medicine) ■ prescription anti-infective (antibiotic) or HIV (infectious) medicines <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ you have heartburn continuously 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 dizziness <p>If pregnant or breastfeeding, ask a health professional before use.</p>
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CODE AREA

: 401374 FA CBP1-F-F



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Omeprazole Delayed Release Tablets 20mg

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

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



14 Tablets

Coated with **Wildberry Mint Flavor**

One 14-day course of treatment

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: 6.5 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

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current labeling information, please visit <https://www.fda.gov/drugs>

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

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

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 880036, El Paso, TX 79888-0036

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

Coated with Wildberry Mint Flavor

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)

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 and 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

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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



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12-9-14

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

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 1/1000th 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 clobazol (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

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

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

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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)



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

FDA Approved

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 Tablets



Coated with **Wildberry Mint Flavor**

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

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 Hakdima 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



Coated with Wildberry Mint Flavor

SWALLOW - DO NOT CHEW

28 ~~14~~ Tablets

Two ~~One~~ 14-day courses of treatment
 2 ~~1~~ 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



LOT NO.

CODE AREA

EXP.

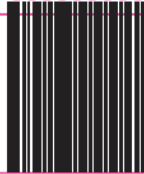
: 40106 FA CBP1-D

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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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

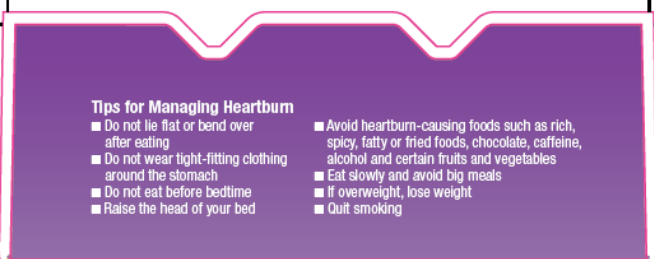
Warnings

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 ▶



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 ~~1~~ BOTTLES INSIDE



LOT NO.

CODE AREA

EXP.

: 401D6 FA CBP1-E

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



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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 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

NDC 0000-000-00

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

Coated with
Wildberry Mint Flavor

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

TreatMyHeartburn.com

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

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LOT NO.

EXP.

: 401D6 FA CBP1-B

CODE AREA

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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

This label may not be the latest approved by FDA.
For more 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 CP1

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 20mg

Drug Facts (continued)

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 nighttime aches, 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

unexplained weight loss

nausea or 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-yeast medicines
- diapam (anxiety medicine)
- gynin (birth control)
- lactulose (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Use

- treats the 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

Active ingredient (in each tablet).....Acid reducer

Omeprazole 20 mg

Purpose

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), 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.

Repeated 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)

Inactive ingredients

bonyl alcohol, calcium, camauha wax, FD&C Blue #2, indigo carmine aluminum lake, iron, hypromellose, hypromellose acetate, lactulose, lactose monohydrate, methyl, 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

CODE AREA

Manufactured by:
Coxsack Pharma Technologies Ltd.
10 Hakdima Street, Yotvata, 20692, Israel

14355 FA CBP1-D

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Omeprazole Delayed Release Tablets 20mg

0000000000

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

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

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**

CODE AREA

Drug Facts (continued)
Inactive ingredients
benzylalcohol, camphor, carnauba wax, FD&C blue #2, hydroxyethylcellulose, hypromellose, hypromellose acetate succinate, lactose monohydrate, methylcellulose, modified starch, monobasic potassium phosphate, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearate, sodium stearate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-719-9260

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

Purpose
Treats frequent heartburn (occurs 2 or more days a week) that is not relieved by antacids. This drug may also be used to treat heartburn (acid reflux) that occurs 2 or more days a week.

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.
■ 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 chest pain
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ to match pain

Ask a doctor or pharmacist before use if you are taking:
■ warfarin, clopidogrel or clostridium difficile (C. diff) antibiotics
■ prescription anti-fungal or anti-yeast medicines
■ prescription anti-biologics (biologics)
■ diazepam (Valium)
■ digoxin (Lanoxin)
■ tacrolimus (Prograf)
■ prescription anti-bronchodilators (medicines for asthma or COPD)
■ prescription anti-epileptics (medicines for seizures)

Use
Treats frequent heartburn (occurs 2 or more days a week) that is not relieved by antacids. This drug may also be used to treat heartburn (acid reflux) that occurs 2 or more days a week.

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
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ to match pain

Ask a doctor or pharmacist before use if you are taking:
■ warfarin, clopidogrel or clostridium difficile (C. diff) antibiotics
■ prescription anti-fungal or anti-yeast medicines
■ prescription anti-biologics (biologics)
■ diazepam (Valium)
■ digoxin (Lanoxin)
■ tacrolimus (Prograf)
■ prescription anti-bronchodilators (medicines for asthma or COPD)
■ prescription anti-epileptics (medicines for seizures)

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

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Manufactured by:
Dexced Pharma Technologies Ltd.
10 Harklams Street, Yokneam, 20692, Israel

Made in Israel

40155 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

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
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

CODE AREA

Drug Facts (continued)

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

Purpose
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 when seeing, 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 clostridium (blood-thinning medicines) or prescription anti-ulcer or anti-acid medicines

Diarrhea (acute or chronic)
diarrhea (acute or chronic)

Ask a doctor or pharmacist before use if you are taking
tacrolimus (immune system medicine), dexamethasone (steroid medicine), or other drugs that may interact with omeprazole.

Other information
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
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.

Other information
Read the directions and warnings before use
Keep the container it contains in original form for information and protection from moisture
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 more than 14 days
you need to take this product 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)

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets
Three 14-day courses of treatment

Coated with **Wildberry Mint Flavor**

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

28 + 14 FREE

NDC 00000-000-00

Treat My Heartburn.com

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

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 (Club Size)

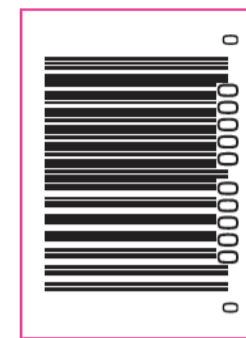
Manufactured by:
 Dexcel Pharma Technologies Ltd,
 10 Hakdima Street, Yokneam, 20692, Israel

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.

<p>Drug Facts (continued)</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 ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. <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>Inactive ingredients</p> <p>benzyl alcohol, carmine, carnuba wax, FD&C blue #2/indigo carmine, aluminum lake, flavor, hypromellose, hydroxypropyl methylcellulose, 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>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Omeprazole 20 mg..... Acid reducer</p> <p>Purpose</p> <p>Use</p> <ul style="list-style-type: none"> ■ 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>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 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 light-headedness ■ 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 anti-fungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription anti-retroviral (medicines for HIV infection) <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>
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CODE AREA

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

Value Pack!
 3-14 Tablet Cartons



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 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:

TITLE: 13 pt Helvetica Neue 77 Bold Cond Oblique

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HEADINGS: 10 pt Helvetica Neue 77 Bold Cond Oblique

SUBHEADINGS: 8 pt Helvetica Neue 77 Bold Cond

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LEADING: 8.7 pt

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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.
For current labeling information, please visit <https://www.fda.gov/drugsatf>

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

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

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



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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)

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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
■ 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.



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0 00000 00000 0

LOT NO.

EXP.

: 40107 FA C1

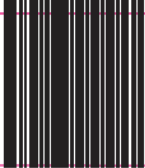
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STANDARD FORMAT

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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 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 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

FDA Approved Treats Frequent Heartburn! Occurring 2 Or More Days a Week

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

Omeprazole Delayed Release Tablets 20mg

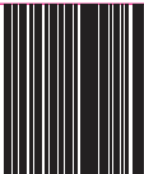

Coated with Wildberry Mint Flavor

Acid Reducer
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.

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

CODE AREA

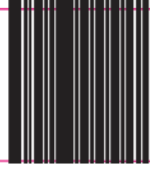


STANDARD FORMAT

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SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
TEXT: 6 pt Helvetica Neue 57 Cond
LEADING: 6.5 pt
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HAIRLINES: 0.5 pt

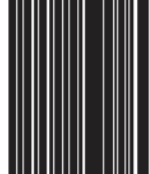
Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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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 	
Questions or comments? 1-800-719-9260		Questions or comments? 1-800-719-9260	

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

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**

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

Coated with **Wildberry Mint Flavor**

42 ~~28~~ Tablets

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

CODE AREA

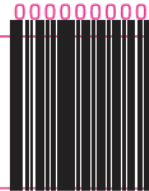
LOT NO.
EXP.
: 401D7 FA C8P1-D

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

STANDARD FORMAT

TYPE SIZES:
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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)



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. 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

Bonus! 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 ~~28~~ Tablets

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

Coated with
Wildberry Mint Flavor

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
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)

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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 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

Other information
 ■ 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

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-000-00

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

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-B

CODE AREA

STANDARD FORMAT
TYPE SIZES:
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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)

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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 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 Hakiddma 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

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

Coated with Wildberry Mint Flavor

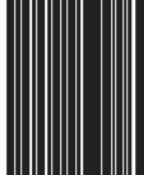
SWALLOW - DO NOT CHEW

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.

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LOT NO. **CODE AREA**

EXP. : 401D7 FA CBP1-C

STANDARD FORMAT

TYPE SIZES:
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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)

<p>000000000</p> 		<p>0000000000</p> 	
<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Omeprazole 20 mg.....Acid reducer</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 steryl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9260</p> <p>Made in Israel 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>Triple Pack Three 14-day courses of treatment</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>Coated with Wildberry Mint Flavor</p> <p>TreatMyHeartburn.com</p> <p>00-0000-0000-00</p>		<p>Safety Feature - Do not use if printed seal under cap is broken or missing.</p> <p>LOT NO.</p> <p>EXP.</p> <p>: 401D7 FA CBP1-G</p> <p>CODE AREA</p> <p>000000000000</p>	

STANDARD FORMAT

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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)



<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg</p> <p>Purpose Acid reducer</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 Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam, 20692, Israel</p>	<p style="text-align: right;">NDC 0000-000-00</p> <p style="text-align: center;">3 PACK Three 14-day courses of treatment</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">DIE CUT WINDOW</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">DIE CUT WINDOW</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">DIE CUT WINDOW</div> </div> <p style="text-align: right;">Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p> <div style="text-align: right;">  </div> <p style="text-align: center;">Omeprazole Delayed Release Tablets 20mg</p> <p style="text-align: center;">Acid Reducer</p> <p style="text-align: center;">SWALLOW - DO NOT CHEW</p> <p style="text-align: center;">42 Tablets Three 14-day courses of treatment 3 BOTTLES INSIDE</p> <p style="text-align: center;">Coated with Wildberry Mint Flavor</p> <div style="text-align: center;">  </div> <p style="text-align: center;">LOT NO.</p> <p style="text-align: center;">EXP.</p> <p style="text-align: center;">: 401D7 FA CBP1-A</p> <p style="text-align: center; font-size: 2em;">CODE AREA</p>
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STANDARD FORMAT

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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

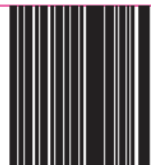
Safety Feature - Do not use if printed seal under cap is broken or missing.

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.....	PurposeAcid reducer
Use	
<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 	
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	
<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 	
Ask a doctor or pharmacist before use if you are taking	
<ul style="list-style-type: none"> ■ warfarin, clopidogrel or clobazam (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	
<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 	
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	
<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 	
14-Day Course of Treatment	
<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. 	
Repeated 14-Day Courses (if needed)	
<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. Heartburn in children may sometimes be caused by a serious condition.	
Other information	
<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 	

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

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

LOT NO.
EXP.
: 40107 FA CBP1-J

CODE AREA

00000000000000000000

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
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) Peel Off Coupon

FRONT PANEL

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**

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

401D7 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.

Omeprazole Delayed Release Tablets 20 mg 42 Count

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 88588-0036



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