

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

Proposed Draft Labeling

NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg

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



14 Tablets

One 14-day course of treatment

: 91574 FA CP1

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. Coupon is
non-reproducible. Coupons
cannot be combined. Mail
properly handled coupons to:

SBF, 815 E. Crosstown Pkwy
PMB 50502, Kalamazoo, MI
49001-2505

**COUPON NOT SUBJECT
TO DOUBLING**
Customer pays any sales tax.



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

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

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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

TreatMyHeartburn.com

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



14 Tablets
One 14-day course of treatment

1 BOTTLE INSIDE

: 915D5 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. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: SBF, 815 E. Crossstown Pkwy PMB 55502, Kalamazoo, MI 49001-2505



0 00000 00000 0

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

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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



28 Tablets

Two 14-day courses of treatment

91530 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. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to:

SBF, 815 E. Crosstown Pkwy
PMB 50502, Kalamazoo, MI
49001-2505

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



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

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

**Proposed Draft Labeling
NDA 22-032**

**Omeprazole Delayed Release Tablets, 20 mg
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



**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



: 915D6 FA C1

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

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. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to:

SBF, 815 E. Crosstown Pkwy
PMB 50502, Kalamazoo, MI
49001-2505

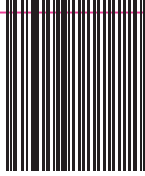
COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



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

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

000000000



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 ■ you get diarrhea

- 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

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

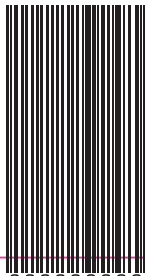
- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

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 or crush 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.



000000000

Drug Facts (continued)

Other information

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

Inactive ingredients

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?
1-800-719-9260

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

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

Tips for Managing Heartburn

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

NDC 0000-000-00

14 FREE

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

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE



0 000000 000000 0

LOT NO.

EXP.

: 915D6 FA C61

CODE AREA

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
42 Tablets (Bottle Carton)



Drug Facts

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

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

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

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

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

Drug Facts (continued)

Stop use and ask a doctor if
■ you get diarrhea
■ 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
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 or crush tablets

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

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

Drug Facts (continued)

Inactive ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?
1-800-719-9260

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

Tips for Managing Heartburn

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

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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



42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE



LOT NO.

EXP.

: 91507 FA CB1-B

CODE AREA

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond Oblique
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 current labeling information, please visit <https://www.fda.gov/drugsatf>

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg
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



42 Tablets

Three 14-day courses of treatment

: 91555 FA CPL

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

Consumer: Only one coupon is redeemable
per purchase. Retailer: This coupon will be
redeemable for face value on specified
products (plus a handling fee) providing
the terms of this offer have
been complied with. Cash
value 1/100th of one cent.
Limit one coupon per
customer. Coupon is
non-reproducible. Coupons
cannot be combined. Mail
properly handled coupons to:

SBF 815 E. Crosstown Pkwy
PMB 50502, Kalamazoo, MI
49001-2505

**COUPON NOT SUBJECT
TO DOUBLING**
Customer pays any sales tax.



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

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

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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



42 Tablets
Three 14-day courses of treatment
3 BOTTLES INSIDE

915D7 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

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. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: SBF, 815 E. Crosstown Pkwy, PMB 50502, Kalamazoo, MI 49001-2505

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



Omeprazole Delayed Release Tablets 20 mg 42 Count

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

000000000



000000000

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

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

Drug Facts (continued)

Inactive ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, 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 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



42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

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

000000000



000000000

000000000

000000000

000000000



LOT NO.

EXP.

: 91507 FA CB1-A

CODE AREA

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond Oblique
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
 42 Tablets Club Size

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

Drug Facts

Active ingredient (in each tablet)
 Omeprazole 20 mg
 Each reduced

Purpose
 Acid reducer

Warnings
 ■ **Do not use if you are allergic to omeprazole.**
 ■ Do not use for more than 14 days unless directed by your doctor.
 ■ Do not take more than 1 tablet a day.
 ■ Swallow whole. Do not chew or crush tablets.

14-Day Course of Treatment
 ■ Swallow 1 tablet with a glass of water before eating in the morning.
 ■ Repeat 14-day courses (if needed).
 ■ You may repeat a 14-day course every 4 months.

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 shortness of breath, sweating, or dizziness.
 ■ chest pain or shoulder pain with shortness of breath, sweating, or dizziness.
 ■ frequent chest pain.
 ■ frequent wheezing, particularly with heartburn.
 ■ frequent weight loss.
 ■ loss of appetite or nausea.
 ■ stomach pain.

Ask a doctor or pharmacist before use if you are taking
 ■ warfarin, clopidogrel or clobazam (blood-thinning medicines).
 ■ prescription antidiabetic (medicines for high blood sugar) or insulin.
 ■ digoxin (heart medicine).
 ■ barbiturates (anesthetic medicines for HIV infection).
 ■ prescription antiretroviral (medicines for HIV infection).

Stop use and ask a doctor if
 ■ you get diarrhea.
 ■ you get stomach pain or nausea.
 ■ you have heartburn for more than 14 days.
 ■ you need to take more than 1 course of treatment every 4 months.

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)

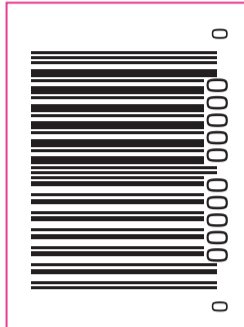
Other information
 ■ Keep the carton. It contains important information.
 ■ Read the directions and warnings before use.
 ■ Store at 20° to 25° C (68° to 77° F) and protect product from moisture.

Inactive ingredients
 carboxymethylcellullose calcium, ferric oxide red, ferric oxide yellow, hydroxypropylmethylcellullose acetate succinate, lactose monohydrate, monohydroxydimethylglycine, glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate.

Questions or comments? 1-800-719-9280

Tips for Managing Heartburn
 ■ Do not lie or bend over after eating.
 ■ Do not wear tight-fitting clothing around the stomach.
 ■ Do not eat spicy, fatty or fried foods.
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods.
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods.
 ■ Eat slowly and avoid big meals.
 ■ Quit smoking.

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



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



42 Tablets
 Three 14-day courses of treatment

STANDARD FORMAT
TYPE SIZES:
 TITLE: 10 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 6 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 Oblique
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.7 pt
 BULLETS: 5 pt Square with 2 MS spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 2.0 pt
 HAIRLINES: 0.5 pt

PRINT OUT is 65%

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



Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid 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	
<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) 	
Drug Facts (continued)	
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ you get diarrhea ■ 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 <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>	
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 <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>	
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 carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

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

Value Pack!
3-14 Tablet Bottles

NDC 0000-000-00

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

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets
Three 14-day courses of treatment
3 BOTTLES INSIDE

CODE AREA

LOT NO.
EXP.
: 915D7 FA C61

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
42 Tablets (Bottle Carton)

0000000000

0000000000

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"> you get diarrhea 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
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 <p>frequent chest pain</p> <ul style="list-style-type: none"> 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 or crush tablets <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>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 	
Questions or comments? 1-800-719-9260		<p>Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam, 20692, Israel</p>	

Drug Facts (continued)
Inactive ingredients camauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, 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

3 PACK Three 14-day courses of treatment

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



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



LOT NO.

EXP.

: 915D7 FA CG1-A

CODE AREA

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Cond Oblique
(continued) 8 pt Helvetica Neue 57 Cond
HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond Oblique
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 is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANDREA LEONARD SEGAL
10/29/2012