

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

NDC 00000-000-00

**SAVE \$X NOW!**  
On This Purchase

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

# Omeprazole Delayed Release Tablets 20mg

**Acid Reducer**



**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<sup>XX</sup>** 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**

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

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<sup>XX</sup>** on your next purchase of  
14 COUNT SIZE  
"Store Brand" Omeprazole  
Delayed Release Tablets 20 mg

Consumer: Only one coupon is redeemable  
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SBE, 815 E. Crosstown Pkwy  
PMB 50502, Kalamazoo, MI  
49001-2505

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



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 C1

BACK PANEL

**SAVE \$X NOW!**

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

**SAVE \$X<sup>XX</sup>** 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  
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PMB 50502, Kalamazoo, MI  
49001-2505

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Customer pays any sales tax.



0 00000 00000 0

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

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**



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

: 915D6 FA C1

**BACK PANEL**

**SAVE \$X NOW!**

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

**SAVE \$X<sup>XX</sup>** 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)**



**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**

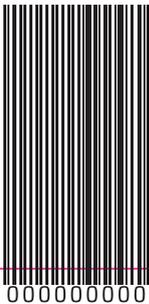
- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

**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.



**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

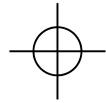
**Questions or comments?**

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

NDC 0000-000-00

**14 FREE**

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

**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



LOT NO.

EXP.

: 915D6 FA CBI

CODE AREA

**STANDARD FORMAT**

**TYPE SIZES:**

**TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique**

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

**(continued) 8 pt Helvetica Neue 57 Cond**

**HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique**

**SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond**

**TEXT: 6 pt Helvetica Neue 57 Cond**

**LEADING: 6.5 pt**

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

**TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond**

**HEAVY LINES: 1.5 pt**

**HAIRLINES: 0.5 pt**

**Proposed Draft Labeling  
NDA 22-032  
Omeprazole Delayed Release Tablets, 20 mg  
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:  
**Dexel Pharma Technologies Ltd.**  
10 Hakidma Street, Yokneam, 20692, Israel

NDC 0000-000-00

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

**14 FREE**

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

**Treat My Heartburn.com**

**Omeprazole Delayed  
Release Tablets 20 mg**

**Acid Reducer**

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

0 000000 000000 0

**LOT NO.**

**EXP.**

: 915D7 FA C81-B

**CODE AREA**

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

**STANDARD FORMAT**

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

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



: 91555 FA CP1



**42 Tablets**

Three 14-day courses of treatment

BACK PANEL

**SAVE \$X NOW!**

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

**SAVE \$X<sup>XX</sup>** 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) 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**



**Omeprazole Delayed  
Release Tablets 20mg**

**Acid Reducer**



: 915D7 FA CPL

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

BACK PANEL

**SAVE \$X NOW!**

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

**SAVE \$X<sup>XX</sup>**

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

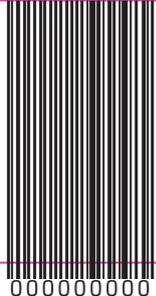
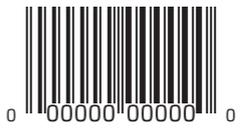
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PMB 58502, Kalamazoo, MI  
49001-2505

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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)**

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<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Omeprazole 20 mg.....</p> <p><b>Purpose</b> Acid reducer</p> <p><b>Use</b></p> <ul style="list-style-type: none"> <li>■ treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p><b>Do not use</b> 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><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent <b>chest pain</b></li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting</li> <li>■ stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ diazepam (anxiety medicine)</li> <li>■ digoxin (heart medicine)</li> <li>■ tacrolimus (immune system medicine)</li> <li>■ prescription antiretrovirals (medicines for HIV infection)</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ you get diarrhea</li> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you need to take more than 1 course of treatment every 4 months</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ for adults 18 years of age and older</li> <li>■ this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</li> </ul> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ swallow 1 tablet with a glass of water before eating in the morning</li> <li>■ take every day for 14 days</li> <li>■ do not take more than 1 tablet a day</li> <li>■ do not use for more than 14 days unless directed by your doctor</li> <li>■ swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ <b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></li> </ul> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions and warnings before use</li> <li>■ keep the carton. It contains important information.</li> <li>■ store at 20-25°C (68-77°F) and protect from moisture</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients:</b> 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</p> <p><b>Questions or comments?</b> 1-800-719-9260</p> <p>Made in Israel Manufactured by: <b>Dexcel Pharma Technologies Ltd.</b> 10 Hakidma Street, Yokneam, 20692, Israel</p>	<p>NDC 00000-000-00</p> <p><b>28 + 14 FREE</b></p> <p>Treats <b>Frequent Heartburn!</b> Occurring <b>2 Or More Days a Week</b></p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; text-align: center;"><b>DIE CUT WINDOW</b></div> <div style="border: 1px solid black; padding: 5px; text-align: center;"><b>DIE CUT WINDOW</b></div> <div style="border: 1px solid black; padding: 5px; text-align: center;"><b>DIE CUT WINDOW</b></div> </div> <p align="right"></p> <p align="center"><b>Omeprazole Delayed Release Tablets 20mg</b></p> <p align="center"><b>Acid Reducer</b></p> <p align="right">42 Tablets Three 14-day courses of treatment <b>3 BOTTLES INSIDE</b></p> <p align="center"></p>	
 0000000000		 0 000000 000000 0	<p>LOT NO.</p> <p>EXP.</p> <p>: 915D7 FA CBL-A</p> <p align="center"><b>CODE AREA</b></p>	

**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)**

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<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Omeprazole 20 mg.....Acid reducer</p> <p><b>Purpose</b> Acid reducer</p> <p><b>Use</b></p> <ul style="list-style-type: none"> <li>■ treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p><b>Do not use</b> 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><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent <b>chest pain</b></li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting</li> <li>■ stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ diazepam (anxiety medicine)</li> <li>■ digoxin (heart medicine)</li> <li>■ tacrolimus (immune system medicine)</li> <li>■ prescription antiretrovirals (medicines for HIV infection)</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ you get diarrhea</li> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you need to take more than 1 course of treatment every 4 months</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ for adults 18 years of age and older</li> <li>■ this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</li> </ul> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ swallow 1 tablet with a glass of water before eating in the morning</li> <li>■ take every day for 14 days</li> <li>■ do not take more than 1 tablet a day</li> <li>■ do not use for more than 14 days unless directed by your doctor</li> <li>■ swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ <b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></li> </ul> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions and warnings before use</li> <li>■ keep the carton. It contains important information.</li> <li>■ store at 20-25°C (68-77°F) and protect from moisture</li> </ul>
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**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 0000-000-00

**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**

**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



0 00000 00000 0

LOT NO.

CODE AREA

EXP.

: 915D7 FA CG1

**STANDARD FORMAT**

**TYPE SIZES:**

**TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique**

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

**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)**

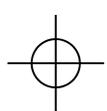
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**Questions or comments?**  
1-800-719-9260

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 Manufactured by:  
 Dexcel Pharma Technologies Ltd.  
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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

NDC 0000-000-00

**3 PACK** Three 14-day courses of treatment

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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

**Safety Feature -**  
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**HAIRLINES:** 0.5 pt

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANDREA LEONARD SEGAL  
10/29/2012