

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
14 Tablets (Blister Foil)

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

Omeprazole DR Tablets
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Technologies Ltd.
10 Hakidma Street,
Yokneam 2069200, Israel

Swallow whole.
Do not chew or crush 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.
91574 00 X10

Omeprazole DR Tablets
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Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
14 Tablets (Bottle Label)

<p>Drug Facts</p> <table border="1"><tr><td>Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</td><td>Purpose</td></tr><tr><td>Use</td><td>■ treats frequent heartburn (occurs 2 or more days a week)</td></tr><tr><td></td><td>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</td></tr></table> <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>Questions? 1-800-719-9280</p>	Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer	Purpose	Use	■ treats frequent heartburn (occurs 2 or more days a week)		■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	<p>Safety Feature – Do not use if printed seal under cap is broken or missing. This label does not contain full product information. See carton for complete information. Read warnings and directions on carton before use. Retain carton for reference.</p>	<p>NOT FOR RESALE</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p> <p>Omeprazole Delayed Release Tablets 20mg</p> <p>Acid Reducer</p> <p>14 Tablets One 14-day course of treatment</p> 	<p>Manufactured by: Pfizer Pharmaceuticals Ltd. 10 Hadassah Street, Yokneam 20109200, Israel Made in Israel</p> <p>CODE AREA</p> <p>• no varnish • no color</p> <p>: 91505 FA F9</p>
Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer	Purpose								
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								

MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique

HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.0 pt

5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
14 Tablets (Inner Carton)

<p>Questions or comments? 1-800-719-9260</p> <p>Inactive ingredients carmelumina wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monohydroxyamine, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, titanium dioxide, triethyl citrate</p> <p>Other information</p> <p>Keep the carton. It contains important information and warnings before use.</p> <p>Read the directions and warnings before use.</p> <p>Store at 20-25°C (68-77°F) and protect from moisture.</p>	<p>Use ■ treats frequent heartburn (occurs 2 or more days a week)</p> <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Do not use if you have trouble or pain swallowing food, vomiting, or chest pain or shoulder pain with shortness of breath, sweating, heartburn with lightheadedness, sweating or dizziness, or fainting.</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, or fainting. ■ chest pain or shoulder pain with shortness of breath, sweating, or fainting. ■ 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 closozol (blood-thinning medicines) ■ prescription antifungal or anti-least medicines ■ dactapan (antibiotic medicine) ■ digoxin (heart medicine) ■ cyclosporin or mycophenolate mofetil (immunosuppressant medicines) ■ prescription antiretroviral (medicines for HIV infection) ■ methotrexate (arthritis medicine) <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 ■ you develop a rash or joint pain <p>If pregnant or breast-feeding, ask a health professional before use.</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>■ it may 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> <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 <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>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg</p> <p>Purpose Acid reducer</p>
<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away. (1-800-222-1222)</p>	<p>Batch No. EXP 43574 00 VA</p> <p>CODE AREA</p> <p>Safety Feature - Do not use if printed tablet blister unit is open or torn.</p>

NOT FOR RESALE

Made in Israel

Manufactured by:
Dexel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 2069200, Israel

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

Omeprazole

delayed release tablets 20 mg
acid reducer



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 Condensed Oblique
- TITLE (continued):** 7 pt Helvetica Neue 77 Bold Condensed Oblique
- (continued):** 7 pt Helvetica Neue 57 Condensed
- HEADINGS:** 7 pt Helvetica Neue 77 Bold Condensed Oblique
- SUBHEADINGS:** 6 pt Helvetica Neue 77 Bold Condensed
- TEXT:** 6 pt Helvetica Neue 57 Condensed
- LEADING:** 6.3 and 6.5 pt
- BULLETS:** 5 pt Square with 2 M'S spacing between statements
- TELEPHONE #:** 6 pt Helvetica Neue 77 Bold Condensed
- HEAVY LINES:** 1.5 pt
- HAIRLINES:** 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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
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- 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:
Dececal Pharma Technologies Ltd.
10 Hakdama Street, Yokneam, 2092000, Israel

Made in Israel

<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</p> <p>■ It may 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 ■ 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</p> <p>■ swallow whole. Do not chew or crush tablets</p> <p>Repeated 1-4 Day Courses (if needed) ■ you may repeat a 1-4 day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture</p> <p>Inactive ingredients canaraba 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>Questions or comments? 1-800-719-9260</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings 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 ■ heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>Ask a doctor before use if you are taking ■ warfarin, clopidogrel or clostazolol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines (heart medicines) ■ dazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiarrhythmals (medicines for HIV infection) ■ methotrexate (arthritis medicine)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>
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CODE AREA

: 91574 FA C17



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



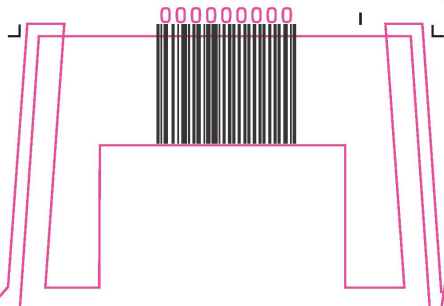
14 Tablets

One 14-day course of treatment

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.3 and 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
14 Tablets (Bottle Carton)



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

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

Drug Facts (continued)

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

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

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
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

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

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

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

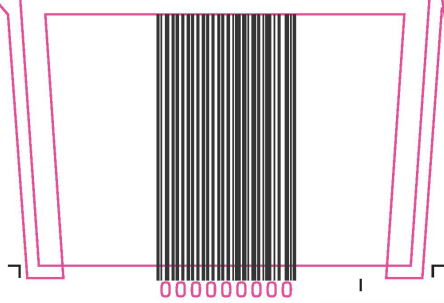
Allergy alert: Do not use if you are allergic to omeprazole

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 cilostazol (blood-thinning medicines) ▶



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LOT NO. **CODE AREA**

EXP.

: 91505 FA C11

MODIFIED FORMAT

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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:
Develcal Pharma Technologies Ltd.
 10 Hakikima Street, Yokneam, 2069200, Israel

Made in Israel

<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 ■ if may 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 ■ 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> <p>Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture</p> <p>Inactive ingredients carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monohydroaluminum polyphosphate, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, 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.....Acid reducer</p> <p>Purpose Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have This may be a sign of a more serious condition. ■ had heartburn over 3 months. ■ 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> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clozapine (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antihepatitis (medicines for HIV infection) ■ methotrexate (arthritis medicine)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>
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CODE AREA

: 91574 FA C4-F



Omeprazole Delayed Release Tablets 20mg

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

FDA Approved

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

MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 7 pt Helvetica Neue 57 Condensed

HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.3 and 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
28 Tablets

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

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

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

Warnings
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
 ■ digoxin (heart medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ prescription antiretrovirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

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

Directions
 ■ for adults 18 years of age and older (every 24 hours), every day
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ 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

CODE AREA

Manufactured by:
Dexcel Pharma Technologies Ltd.
10 Hakdima Street, Yokneam, 2069200, Israel

: 91530 FA C17

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

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

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

Warnings
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
 ■ digoxin (heart medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ prescription antiretrovirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

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

Directions
 ■ for adults 18 years of age and older (every 24 hours), every day
 ■ this product is to be used once a day (every 24 hours), every day for 14 days
 ■ 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

CODE AREA

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

28 Tablets

Two 14-day courses 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

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

TreatMyHeartburn.com

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

NDC 00000-000-00

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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 Pharmaceuticals Ltd.
10 Hakidma Street, Yokneam, 2069200, 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



28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

STANDARD FORMAT

TYPE SIZES:

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
28 Tablets

Omeprazole Delayed Release Tablets 20mg

Drug Facts (continued)

Inactive Ingredients
carrauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

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
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 shoulder, 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)
■ diazepam (anxiety medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antifungal or anti-yeast medicines
■ ginkgo (heart medicine)

Other Information
■ methotrexate (arthritis medicine)
■ prescription antiretrovirals (medicines for HIV infection)

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

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day

Repeated 14-Day Courses (if needed)
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew or crush tablets

Other Information
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more 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.

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

If pregnant or breast-feeding, ask a health professional before use.
■ you get diarrhea ■ you develop a rash or joint pain

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

Drug Facts (continued)

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 shoulder, 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)
■ diazepam (anxiety medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antifungal or anti-yeast medicines
■ ginkgo (heart medicine)

Other Information
■ methotrexate (arthritis medicine)
■ prescription antiretrovirals (medicines for HIV infection)

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

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day

Repeated 14-Day Courses (if needed)
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew or crush tablets


Other Information
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more 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.

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

If pregnant or breast-feeding, ask a health professional before use.
■ you get diarrhea ■ you develop a rash or joint pain

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



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

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

FDA Approved

NDC 00000-000-00


TreatMyHeartburn.com

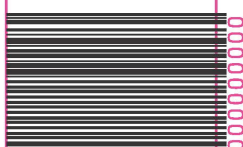
Treats Frequent Heartburn!
Occurring **2 Or More Days a Week**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

28 Tablets
Two 14-day courses of treatment





STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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:
Dexel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 2069200, 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

28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

TreatMyHeartburn.com

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

LOT NO.

EXP.

: 915D6 FA CBP3-F

CODE AREA

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
28 Tablets

Drug Facts (continued)
Inactive ingredients
carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, lactose monohydrate, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

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 arm, neck or shoulders, or lightheadedness

requent 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 clostazolol (blood-thinning medicines)
■ Prescription antifungal or anti-yeast medicines
■ Diazepam (anxiety medicine)
■ Digoxin (heart medicine)
■ Tacrolimus or mycophenolate mofetil (immune system medicines)
■ Prescription antiretrovirals (medicines for HIV infection)
■ Methotrexate (arthritis medicine)

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

Omeprazole Delayed Release Tablets 20 mg

CODE AREA

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

1530 FA C4-B



Omeprazole Delayed Release Tablets 20 mg

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**

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 Tablets

Two 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
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BULLETS: 5 pt Square with 2 M'S spacing between statements
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HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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, 2069200, 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**

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

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 ▶

STANDARD FORMAT

TYPE SIZES:

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

Final Printed 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 clobazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

camauaba 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, 2069200, 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



28 14 Tablets

Two ~~One~~ 14-day courses of treatment
2 BOTTLES INSIDE

Drug Facts

Active ingredient	Purpose
Omeprazole 20 mg.....	Acid reducer

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

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

STANDARD FORMAT

TYPE SIZES:

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
28 Tablets

**Omeprazole Delayed
Release Tablets 20 mg**

CODE AREA

Drug Facts (continued)
Inactive ingredients
carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, hypromellose acetate succinate, sodium starch glycolate, sodium stearoyl fumarate, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

Drug Facts (continued)
Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer
Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
Allergy alert: Do not use if you are allergic to omeprazole 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.
■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain
Ask a doctor or pharmacist before use if you are taking
■ proton pump inhibitors (blood-thinning medicines)
■ proton pump inhibitors or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)
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
Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea ■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)
Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew 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

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

PL550 FA CH-E



**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

Bonus! 14 Free

NDC 00000-000-00



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



28 ~~14~~ Tablets

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

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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 clostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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, 2069200, Israel

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

28 ~~14~~ Tablets

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

NDC 0000-000-00

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

000000000

LOT NO.

EXP.

: 915D6 FA C4-E

CODE AREA

STANDARD FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

**Omeprazole Delayed
Release Tablets 20 mg**

CODE AREA

Drug Facts (continued)
Inactive ingredients
carnuba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

Drug Facts
Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer
Use
■ treats frequent heartburn (occurs **2 or more** days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
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 arm, 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antivirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)
Other information
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ you may repeat a 14-day course every 4 months
Repeated 14-Day Courses (if needed)
■ do not use for more than 14 days unless directed by your doctor
■ do not take more than 1 tablet a day
■ take every day for 14 days
■ the morning
■ swallow 1 tablet with a glass of water before eating in the morning
14-Day Course of Treatment
■ relief of symptoms within 24 hours
■ if you take 1 to 4 days for full effect, some people get complete relief of symptoms within 24 hours
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
Directions
■ Stop use and ask a doctor if your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)
Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)
Directions
■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ if you take 1 to 4 days for full effect, some people get complete relief of symptoms within 24 hours
■ swallow 1 tablet with a glass of water before eating in the morning
14-Day Course of Treatment
■ 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

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

91555 FA C17



**Omeprazole Delayed
Release Tablets 20 mg**

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

Tips for Managing Heartburn

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



NDC 00000-000-00

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

**Omeprazole Delayed
Release Tablets 20 mg**

Acid Reducer



42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

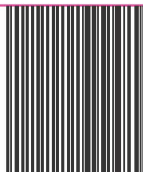
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

000000000



Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer		Stop use and ask a doctor if	
Purpose		<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 ■ you develop a rash or joint pain 	
Use		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)	
<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 		Directions	
Warnings		<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 	
Allergy alert: Do not use if you are allergic to omeprazole		14-Day Course of Treatment	
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.		<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 	
Ask a doctor before use if you have		Repeated 14-Day Courses (if needed)	
<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 		<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. 	
Ask a doctor or pharmacist before use if you are taking		Other information	
<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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) 		<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 	



000000000

Tips for Managing Heartburn

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

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



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 Pharmaceuticals Ltd.
10 Hakidma Street, Yokneam, 2069200, Israel

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



CODE AREA

LOT NO.

EXP.

: 915D7 FA C11

STANDARD FORMAT

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

**Omeprazole Delayed
Release Tablets 20mg**

CODE AREA

Drug Facts (continued)
Inactive ingredients
canabax wax, ferric oxide red, ferric oxide yellow, hypromellose acetate succinate, lactose monohydrate, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

Drug Facts (continued)
Active ingredient (in each tablet)
Omeprazole 20 mg.....Acid reducer
Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)
Other information
■ Keep the carton. It contains important information.
■ Store at 20-25°C (68-77°F) and protect from moisture.
Directions
■ For adults 18 years of age and older
■ This product is to be used once a day (every 24 hours), every day for 14 days
■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
■ Swallow 1 tablet with a glass of water before eating in the morning
■ Do not take more than 1 tablet a day
■ Do not use for more than 14 days unless directed by your doctor
■ Do not chew 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.
Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

91555 FA C4-F



**Omeprazole Delayed
Release Tablets 20mg**

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

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

FDA Approved

NDC 00000-000-00



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

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000000000

Drug Facts		Drug Facts (continued)	
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		Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain	
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.		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)	
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		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.	
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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)		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:
Dexxel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 2069200, 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

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE



LOT NO.

EXP.

: 915D7 FA C4-F

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

Drug Facts (continued)
carruba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, polyethylene glycol, 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

CODE AREA

Drug Facts (continued)

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

Purpose Acid reducer

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

Warnings 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
■ stomach pain
■ nausea or vomiting

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 or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

Repeated 14-Day Courses (if needed)
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew or crush tablets
■ take every day for 14 days
■ do not take more than 1 tablet a day

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

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
■ if you take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

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)

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

If pregnant or breast-feeding, ask a health professional before use.

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

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

Made in Israel

: 91555 FA C4-B



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



42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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 clobazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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
■ you develop a rash or joint pain

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

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

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew 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, 2069200, 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**

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

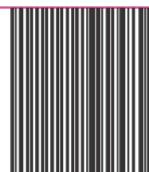
TreatMyHeartburn.com

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

0 00000 00000 0

LOT NO.
EXP.
: 915D7 FA C4-B

CODE AREA



000000000

STANDARD FORMAT

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

**Omeprazole Delayed
Release Tablets 20 mg**

Drug Facts (continued)
Inactive ingredients (continued)
carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monothanalamine, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole 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 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretroviral (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ do not take more than 14 days unless directed by your doctor

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.

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

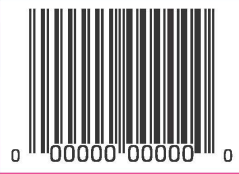
If pregnant or breast-feeding, ask a health professional before use.
■ you get diarrhea
■ you develop a rash or joint pain

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

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

CODE AREA

: 91555 FA C4-D



**Omeprazole Delayed
Release Tablets 20 mg**

**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



42 ~~28~~ Tablets

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

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

000000000

000000000

Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid reducer	<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 you develop a rash or joint pain 	
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 		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 	
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.		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 or crush tablets 	
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 		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. 	
Ask a doctor or pharmacist before use if you are taking <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 or mycophenolate mofetil (immune system medicines) prescription antiretrovirals (medicines for HIV infection) methotrexate (arthritis medicine) 		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, 2069200, 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

42 ~~28~~ Tablets

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

NDC 0000-000-00

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



0 00000 00000 0

LOT NO.

EXP.

: 915D7 FA C4-D

CODE AREA

STANDARD FORMAT

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

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

Omeprazole Delayed Release Tablets 20mg

Drug Facts (continued)

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

Use
 ■ Treats frequent heartburn (occurs 2 or more days a week)
 ■ Take 1 to 4 days for full effect

Warnings
 ■ Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 ■ Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ Heartburn with lightheadedness, sweating or dizziness
 ■ Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulder; 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
 ■ Digoxin (heart medicine)
 ■ Diazepam (anxiety medicine)
 ■ Tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ Prescription antivirals (medicines for HIV infection)
 ■ Methotrexate (arthritis medicine)

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

Directions
 ■ For adults 18 years of age and older
 ■ This product is to be used once a day (every 24 hours), every day for 14 days
 ■ If you have heartburn over 3 months, see your doctor.
 ■ 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

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)


If pregnant or breast-feeding, ask a health professional before use.

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

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)

CODE AREA

Omeprazole Delayed Release Tablets 20mg




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

Tips for Managing Heartburn

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


Bonus! 14 Free NDC 00000-000-00



Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



42 ~~28~~ Tablets
Three ~~two~~ 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

000000000

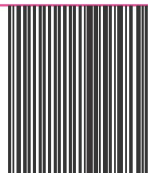


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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)	
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 ■ you develop a rash or joint pain If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew 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, 2069200, Israel



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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

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

42 ~~28~~ Tablets

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

0 00000 00000 0

LOT NO.

EXP.

: 915D7 FA C4-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 Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets



Drug Facts (continued)
Inactive Ingredients
carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

**Omeprazole Delayed
Release Tablets 20 mg**

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

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

Warnings
■ Do not use if you 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 shoulder; 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

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)

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

Drug Facts (continued)
Purpose
Acid reducer

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

CODE AREA

: 91555 FA C4-C



**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

28 + 14 FREE

NDC 00000-000-00



Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



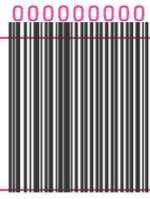
42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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
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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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 ■ you develop a rash or joint pain

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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, 2069200, 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

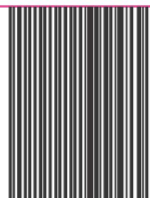
Acid Reducer

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



LOT NO.

EXP.

: 915D7 FA C4-C

CODE AREA

STANDARD FORMAT

TYPE SIZES:

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

Manufactured by:
Chemical Pharmaceutical Technologies Ltd.
 10 Hakhdma Street, Yokneam, 2093200, Israel

Drug Facts (continued)

Directions
 Omeprazole 20 mg (acid reducer)
 this product is to be used once a day (every 24 hours), every day for 14 days

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

Warnings
 May be 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:
 heartburn over 3 months. This may be a sign of a more serious condition.
 heartburn with high blood pressure, sweating or dizziness
 chest pain or trouble with breathing, trouble swallowing, or high blood pressure
 request chest pain
 request wheezing, particularly with heartburn
 request weight loss
 request or vomiting
 stomach pain

Ask a doctor or pharmacist before use if you are taking:
 warfarin, clopidogrel or clopidazole (blood-thinning medicines)
 digoxin (heart medicine)
 diazepam (anxiety medicine)
 prescription antibiotics or anti-fungal medicines
 prescription antiretrovirals (medicines for HIV infection)
 methotrexate (arthritis medicine)

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

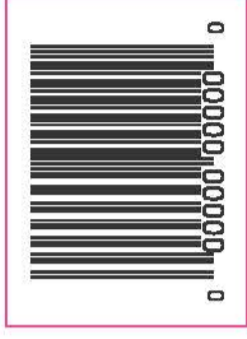
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Other information
 may sometimes be caused by a serious condition.
 children under 18 years of age: ask a doctor. Heartburn in children 4 months unless checked by a doctor.
 do not take for more than 14 days or more often than every 14 days unless checked by a doctor.
 you may need a 14-day course every 4 months.
 Repeat 14-Day Course (if needed)
 swallow whole. Do not chew or crush tablets.
 do not use for more than 14 days unless checked by your doctor.
 do not take more than 1 tablet a day.
 take every day for 14 days.
 swallow 1 tablet with a glass of water before eating in the morning.

Inactive ingredients carmellose gum, ferrous oxide red, ferric oxide yellow, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-779-9299

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.
 Overweight, lose weight.
 Quit smoking.



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

3 PACK Three 14-day courses of treatment

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

STANDARD FORMAT
 TYPE SIZES:
 TITLE: 10 pt Helvetica Neue 77 Bold Condensed Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) & 8 pt Helvetica Neue 57 Condensed
 HEADINGS: 6 pt Helvetica Neue 77 Bold Condensed Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
 TEXT: 6 pt Helvetica Neue 57 Condensed
 LEADINGS: 6.7 pt
 BULLETS: 6 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
 HEAVY LINES: 2 pt
 HAIRLINES: 0.5 pt

PRINT at 65% for 11-inch x 17-inch size paper

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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 ■ you develop a rash or joint pain

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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, 2069200, 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



0 00000 00000 0

LOT NO.

EXP.

: 915D7 FA C4-A

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets

**Omeprazole Delayed
Release Tablets 20 mg**

Drug Facts (continued)
Inactive ingredients
carruba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

Drug Facts (continued)
Active ingredient (in each tablet)
Omeprazole 20 mg, Acid reducer
Use
■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
■ **Do not use** if you have trouble or pain swallowing food, vomiting with blood, or 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 clobazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)
Other information
■ read the directions and warnings before use
■ keep the carton, it contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture
▲

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

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea
■ you get a rash or joint pain
■ you get dizziness
■ you develop a rash or joint pain
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

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

CODE AREA

91555 FA C4-G



**Omeprazole Delayed
Release Tablets 20 mg**

**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

Triple Pack Three 14-day courses of treatment

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

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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 ■ you develop a rash or joint pain

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

Directions

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

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew 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, 2069200, 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

Triple Pack Three 14-day courses of treatment

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-0000-00



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE



LOT NO.

EXP.

: 915D7 FA C4-G

CODE AREA

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

(continued): 8 pt Helvetica Neue 57 Condensed

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

000000000



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 you develop a rash or joint pain
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 	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)
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 or mycophenolate mofetil (immune system medicines) prescription antiretrovirals (medicines for HIV infection) methotrexate (arthritis medicine) 	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:
Dexel Pharma Technologies Ltd.
10 Hakidma Street, Yokneam, 2069200, 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




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



0 000000 000000 0

CODE AREA

LOT NO.

EXP.

: 915D7 FA C4-J

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

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/drugs>

Final Printed Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Blister Foil)

<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>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 X3</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam 2069200, Israel</p>



= No Print Area

Reference ID: 4174190

4-26-17

Final Printed Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
14 Tablets (Bottle Label)

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</p> <p>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</p> <p>Other information ■ Read the directions and warnings before use. ■ Keep the carton, ■ Contains important information, ■ store at 20°-25° C (68°-77° and ■ protect from moisture</p> <p>Questions? 1-800-719-2280</p>	<p>Safety Feature – Do not use if printed seal under cap is broken or missing.</p> <p>This label does not contain full product information. See carton for complete information, read warnings and directions on carton before use. Retain carton for reference.</p>	<p>NOT FOR RESALE</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week.</p> <p>Omeprazole Delayed Release Tablets 20mg</p> <p>Acid Reducer</p> <p>SWALLOW - DO NOT CHEW</p>  <p>Coated with Wildberry Mint Flavor</p> <p>14 Tablets One 14-day course of treatment</p>	<p>Manufactured by: Oxeval Pharma Technologies Ltd. 10 Hakdima Street, Yokneam 2062600, Israel Made in Israel</p> <p>CODE AREA • no varnish • no color : 401D5 FA F3</p>
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MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique

HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.0 pt

UNDERLINES: 0.5 pt

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

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with difficulty or pain swallowing food, vomiting, chest pain or shoulder pain with shortness of breath, sweating, heartburn with lightheadedness, sweating or dizziness</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clostazolol (blood-thinning medicines) ■ prescription anti-fungal or anti-yeast medicines (medicines) ■ dexamethasone (steroid medicine) ■ digoxin (heart medicine) ■ prescription antacids (medicines for stomach acid) ■ prescription anticholinergics (medicines for HIV infection) ■ methotrexate (arthritis medicine)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Batch No. EXP + 40174 00 V3</p> <p style="text-align: center;">CODE AREA</p> <p style="text-align: center;">Safety Feature - Do not use if printed tablet blister unit is open or torn.</p>
<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 in your area. (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 ■ may 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 ■ 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</p> <p>Repeated 14-Day Courses (if needed) ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets.</p> <p>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 in a cool, dry place (68°F-77°F) and protect from moisture ■ store at 20-25°C (68-77°F)</p> <p>Inactive ingredients FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, mannitol, modified starch, monohydroaluminum polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9260</p>	<p>NOT FOR RESALE</p> <p>Made in Israel</p> <p>Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma Street, Yokneam, 2069200, Israel</p>
<p><i>Treats Frequent Heartburn!</i> <i>Occurring 2 or More Days a Week</i></p> <h1 style="margin: 0;">Omeprazole</h1> <p style="margin: 0;">delayed release tablets 20 mg acid reducer</p> <p style="margin: 0;">SWALLOW - DO NOT CHEW</p> <p style="margin: 0;">14 TABLETS</p> <p style="margin: 0;"><i>One 14-day course of treatment</i></p> <p style="margin: 0;">Coated with Wildberry Mint Flavor</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 	

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.3 and 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

4-20-17

Final Printed 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

CODE AREA

Drug Facts

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 are allergic to omeprazole 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 highheadness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

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 or mycophenolate mofetil (immunosuppressant medicines) ■ prescription antiepileptics (medicines for HIV infection) ■ methotrexate (arthritides medicine)

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

If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

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 take more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed) ■ swallow whole. Do not chew, crush, or suck tablets. ■ 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

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

Questions or comments? 1-800-719-9260

Manufactured by: **Coscel Pharma Technologies Ltd.**
10 Hadera Street, Yokneam, 2092000, Israel

Made in Israel

40374 FA CE



Omeprazole Delayed Release Tablets 20 mg

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



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

One 14-day course of treatment







MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique

TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique (continued)

7 pt Helvetica Neue 57 Condensed

HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.3 and 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Final Printed 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 Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
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 Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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
Cesca Pharma Technologies Ltd.
 10 Hakhima Street, Yokneam, 2069200, Israel

Made in Israel

<p>Questions or comments? 1-800-719-9260</p> <p>Inactive ingredients benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, mannitol, polyethylene glycol 350, polyethylene glycol 400, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Other information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) and protect from moisture. ■ keep the carton. It contains important information. ■ read the directions and warnings before use <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 <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ swallow whole. Do not chew, crush, or suck tablets. ■ do not take for more than 14 days unless directed by your doctor ■ 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>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ take 1 to 4 days for full effect</p> <p>Warnings 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 ■ had heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>Heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, or lightheadedness; or ■ pain spreading to arms, neck or shoulder; or lightheadedness</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clostazozol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ prescription antiepileptics (medicines for HIV infection) ■ prescription and birth control (immunosystem medicines) ■ methotrexate (arthritis medicine)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>
<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>■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</p>	<p>Code Area</p> <p>40374 FA CBP2-F</p>



Omeprazole Delayed Release Tablets 20mg

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

FDA Approved

NDC 00000-000-00



Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with Wildberry Mint Flavor

14 Tablets

One 14-day course of treatment

MODIFIED FORMAT

- TYPE SIZES:**
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.3 and 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

000000000

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

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

FDA Approved

DIE CUT WINDOW

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
1 BOTTLE INSIDE

LOT NO. **CODE AREA**

EXP.
: 401D5 FA C4-F

000000000

Drug Facts (continued)

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

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

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 clostazol (blood-thinning medicines)

NDC 0000-0000-00

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
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 Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

Omeprazole Delayed Release Tablets 20mg

CODE AREA

Drug Facts (continued)

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

Questions or comments? 1-800-719-9260

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 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 clostazolol (blood-thinning medicines)
prescription antifungal or anti-yeast medicines
diazepam (anxiety medicine)
digoxin (heart medicine)
lactulose or mycophenolate mofetil (immune system medicines)
prescription antivirals (medicines for HIV infection)
methotrexate (arthritis medicine)

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
swallow 1 tablet with a glass of water before eating in the morning
do not take more than 1 tablet a day
do not use for more than 14 days unless directed by your doctor
swallow whole. Do not chew, crush, or suck tablets.
Repeated 14-Day Courses (if needed)
you may repeat a 14-day course every 4 months
do not take for more than 14 days or more often than every 4 months unless directed by a doctor
children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

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

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


Omeprazole Delayed Release Tablets 20mg



Tips for Managing Heartburn

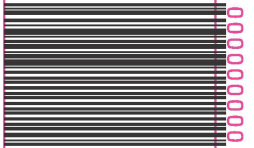
- Do not lie flat or bend over after eating
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Do not wear tight-fitting clothing around the stomach
- Eat slowly and avoid big meals
- Do not eat before bedtime
-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

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

28 Tablets

Two 14-day courses of treatment

Coated with **Wildberry Mint Flavor**

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)
Other information

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

Inactive ingredients
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, 2069200, 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**

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

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

**Omeprazole Delayed
Release Tablets 20 mg**

CODE AREA

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

Questions or comments? 1-800-719-9260

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

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

Warnings
Do not use if you 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
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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Allergy alert Do not use if you are allergic to omeprazole

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
■ Swallow 1 tablet with a glass of water before eating in the morning
■ Do not take more than 1 tablet a day
■ Do not take more than 14 days unless directed by your doctor
■ 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.

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

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

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

40130 FA CH-F



**Omeprazole Delayed
Release Tablets 20 mg**

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

Tips for Managing Heartburn

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

FDA Approved NDC 00000-000-00



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

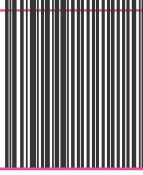
28 Tablets

Two 14-day courses of treatment

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
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SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

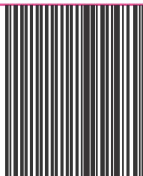
- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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



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Drug Facts (continued)

Other information

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

Inactive ingredients

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, 2069200, 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



Coated with **Wildberry Mint Flavor**

28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE



LOT NO.

EXP.

: 401D6 FA C4-F

CODE AREA

Drug Facts

Active ingredient	Purpose
Omeprazole 20 mg	Acid reducer

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

STANDARD FORMAT

TYPE SIZES:

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

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

Drug Facts (continued)
Inactive Ingredients benzyl alcohol, carnuba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, 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

Drug Facts (continued)

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

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

Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
Had heartburn over 3 months. This may be a sign of a more serious condition.
Heartburn with lightheadedness, sweating or dizziness
Chest pain or shoulder pain with shortness of breath, sweating, fainting, or dizziness, particularly with heartburn
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 or mycophenolate mofetil (immune system medicines)
Prescription antiretrovirals (medicines for HIV infection)
Methotrexate (arthritis medicine)

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, fainting, or dizziness, particularly with heartburn
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 or mycophenolate mofetil (immune system medicines)
Prescription antiretrovirals (medicines for HIV infection)
Methotrexate (arthritis medicine)

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

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
You develop a rash or joint pain

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

Omeprazole Delayed Release Tablets 20mg

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

CODE AREA

40130 FA C4-B



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**

28 Tablets

Two 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
 ■ prescription antiretrovirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)
Stop use and ask a doctor if ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you need to take more than 1 course of treatment every 4 months
 ■ you get diarrhea ■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

Drug Facts (continued)
Other information
 ■ read the directions and warnings before use
 ■ keep the carton. It contains important information.
 ■ store at 20-25°C (68-77°F) and protect from moisture
Inactive ingredients
 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, 2069200, 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

DIE CUT WINDOW

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

DIE CUT WINDOW

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

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.

EXP.

: 401D6 FA C4-B

CODE AREA

STANDARD FORMAT

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

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

Omeprazole Delayed Release Tablets 20mg

Drug Facts (continued)

Inactive Ingredients
benzyl alcohol, 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

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 anti-thrombotic medicines
■ prescription antifungal or anti-yeast medicines
■ diltiazem (heart medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

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.

CODE AREA

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

Made in Israel

40130 FA C4-D



0 000000 000000 0

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

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



Coated with **Wildberry Mint Flavor**

28 ~~14~~ **Tablets**

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

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

Other information

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

Inactive ingredients

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, 2069200, Israel

Tips for Managing Heartburn

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

Bonus Pack! 14 Free

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 14 Tablets



Coated with
Wildberry Mint Flavor

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

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

STANDARD FORMAT

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

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

Drug Facts (continued)
Inactive ingredients
benzyl alcohol, carnuba 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, tracefin, triethyl citrate

Questions or comments? 1-800-719-9260

Drug Facts (continued)

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

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

Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or 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 or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

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

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)

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you get diarrhea ■ you develop a rash or joint pain
■ 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

CODE AREA

Manufactured by:
Dexcel Pharma Technologies Ltd.
10 Hakdima Street, Yokneam, 2069200, Israel

Made in Israel

: 40130 FA CH-E

Omeprazole Delayed Release Tablets 20mg



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

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

Bonus! 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



Coated with **Wildberry Mint Flavor**

28 ~~14~~ Tablets

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

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

Other information

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

Inactive ingredients

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, 2069200, Israel

Tips for Managing Heartburn

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

Bonus! 14 Free

DIE CUT WINDOW

DIE CUT WINDOW

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

Treat My Heartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 14 Tablets

Coated with **Wildberry Mint Flavor**

Two ~~One~~ 14-day courses of treatment
2 BOTTLES INSIDE

NDC 0000-000-00

Drug Facts

Active ingredient	Purpose
Omeprazole 20 mg.....	Acid reducer

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

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

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

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

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

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

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
■ you develop a rash or joint pain

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

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 steryl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?
1-800-719-9260

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

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

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

LOT NO.
EXP.
: 403D7 FA C4

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

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

**Omeprazole Delayed
Release Tablets 20 mg**

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

Questions or comments? 1-800-719-9260

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

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 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antivirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

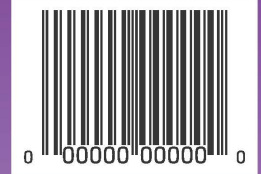
Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 months
■ you get diarrhea ■ you develop a rash or joint pain

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

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

CODE AREA

40355 FA CH-F



**Omeprazole Delayed
Release Tablets 20mg**

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

Tips for Managing Heartburn

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

FDA Approved

NDC 00000-000-00



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

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000000000

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 ■ you develop a rash or joint pain
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 	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)	
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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) 	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, 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>
		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, 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, 2069200, 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

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Coated with
Wildberry Mint Flavor



CODE AREA

LOT NO.

EXP.

: 401D7 FA C4-F

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

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

Omeprazole Delayed Release Tablets 20 mg

Drug Facts (continued)

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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole 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 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 or mycophenolate mofetil (immune system medicines)
■ prescription antivirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

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

14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor

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.

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)

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

If pregnant or breast-feeding, ask a health professional before use.

CODE AREA



Omeprazole Delayed Release Tablets 20 mg


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

Tips for Managing Heartburn

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

NDC 00000-000-00

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

Final Printed 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.....Acid reducer		Stop use and ask a doctor if	
Use		<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 ■ you develop a rash or joint pain 	
Warnings		Directions	
<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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) 		<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>■ for adults 18 years of age and older</p> <p>■ this product is to be used once a day (every 24 hours), every day for 14 days</p> <p>■ it may 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> <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 	

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, 2069200, Israel

14 FREE

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

Wildberry Mint Flavor

Coated with

Tips for Managing Heartburn

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

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

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

0 00000 00000 0

STANDARD FORMAT

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

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

Omeprazole Delayed
Release Tablets 20mg

CODE AREA

Drug Facts (continued)

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

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

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
chest pain
 frequent wheezing, particularly with heartburn
 frequent weight loss
 nausea or vomiting
 stomach pain

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

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

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

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)

Stop use and ask a doctor if
 ■ your heartburn continues or worsens
 ■ you need to take this product for more than 14 days
 ■ you get diarrhea ■ you develop a rash or joint pain
If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

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

Purpose

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

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
chest pain
 frequent wheezing, particularly with heartburn
 frequent weight loss
 nausea or vomiting
 stomach pain

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

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.

Questions or comments? 1-800-719-9280

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, tracefin, triethyl citrate



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

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

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

Coated with **Wildberry Mint Flavor**

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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) 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 cilostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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 ■ you develop a rash or joint pain

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

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

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

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

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

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

Drug Facts (continued)
Inactive ingredients
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, 2069200, 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 **42 ~~28~~ Tablets**

Coated with **Wildberry Mint Flavor**

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

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

NDC 0000-000-00



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LOT NO.
EXP.
: 401D7 FA C4-D

CODE AREA

STANDARD FORMAT

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

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

Omeprazole Delayed
Release Tablets 20mg

Drug Facts (continued)

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

Use
 ■ treats frequent heartburn (occurs **2 or more** days a week)
 ■ 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 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 shoulder; 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
 ■ digoxin (heart medicine)
 ■ diazepam (anxiety medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ prescription antivirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

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

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

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

CODE AREA

Omeprazole Delayed
Release Tablets 20mg

Drug Facts (continued)

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

Use
 ■ treats frequent heartburn (occurs **2 or more** days a week)
 ■ 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 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 shoulder; 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
 ■ digoxin (heart medicine)
 ■ diazepam (anxiety medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ prescription antivirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

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

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

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

CODE AREA

Omeprazole Delayed
Release Tablets 20mg

Drug Facts (continued)

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

Use
 ■ treats frequent heartburn (occurs **2 or more** days a week)
 ■ 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 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 shoulder; 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
 ■ digoxin (heart medicine)
 ■ diazepam (anxiety medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ prescription antivirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

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

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

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

CODE AREA

STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
 HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
 TEXT: 6 pt Helvetica Neue 57 Condensed
 LEADING: 6.5 and 6.7 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Final Printed 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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)	
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 ■ you develop a rash or joint pain If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	
Drug Facts (continued) Inactive ingredients 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, 2069200, Israel	

Tips for Managing Heartburn

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

Bonus! 14 Free

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



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
3 ~~2~~ BOTTLES INSIDE

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



LOT NO.

EXP.

: 401D7 FA C4-E

CODE AREA

STANDARD FORMAT

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

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

Omeprazole Delayed Release Tablets 20mg

CODE AREA

Drug Facts (continued)

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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole 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.
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulder; 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 clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretroviral (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Other information
■ keep the carton, it contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

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

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
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
■ store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients
benzyl alcohol, carmine, 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

Omeprazole Delayed Release Tablets 20mg




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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

28 + 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



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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		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 ■ you develop a rash or joint pain
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 	If pregnant or breast-feeding , ask a health professional before use.	
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 or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) 	Directions	<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> <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>
		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, 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, 2069200, Israel

NDC 0000-000-00 **28 + 14 FREE** **Treats Frequent Heartburn!**
Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg



Acid Reducer
SWALLOW - DO NOT CHEW



42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

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



LOT NO.
EXP.
: 401D7 FA C4-C

CODE AREA

STANDARD FORMAT

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

Final Printed 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

NDC 0000-000-00

3 PACK Three 14-day courses of treatment

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE



Coated with
Wildberry Mint Flavor



CODE AREA

LOT NO.

EXP.

: 401D7 FA C4-A

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

Drug Facts

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

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. 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 or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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 ■ you develop a rash or joint pain

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Other information

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

Drug Facts (continued)

Inactive ingredients

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, 2069200, Israel

STANDARD FORMAT

TYPE SIZES:

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

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

Omeprazole Delayed Release Tablets 20mg

CODE AREA

Drug Facts (continued)

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

Questions or comments? 1-800-719-9260

Drug Facts

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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole 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 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 clobazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Do not use if you have trouble or pain swallowing food, vomiting

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

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)

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

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

Omeprazole Delayed Release Tablets 20mg



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

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- 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

Triple Pack Three 14-day courses of treatment NDC 00000-000-00

TreatMyHeartburn.com Treats Frequent Heartburn! Occurring 2 Or More Days a Week


Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

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



STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed 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) 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 cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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
 - you develop a rash or joint pain

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Other information

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

Drug Facts (continued)

Inactive ingredients

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, 2069200, 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

Triple Pack Three 14-day courses of treatment

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

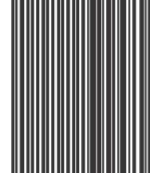


Coated with **Wildberry Mint Flavor**

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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000000000



LOT NO.

EXP.

: 401D7 FA C4-G

CODE AREA

STANDARD FORMAT

TYPE SIZES:

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

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



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 you develop a rash or joint pain
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 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. 	
Warnings		Other information	
<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 or mycophenolate mofetil (immune system medicines) prescription antiretrovirals (medicines for HIV infection) methotrexate (arthritis medicine) 		<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, 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, 2069200, 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

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

TreatMyHeartburn.com

Coated with
Wildberry Mint Flavor

0 00000 00000 0

LOT NO.
EXP.
: 401107 FA C4-J

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

VALERIE S PRATT
10/30/2017