

Proposed Draft 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
20mg
Acid reducer
Push tablet through foil.
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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 X9

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10 Hakidma Street,
Yokneam 2069200, Israel

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

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

<p>Questions? 1-800-719-3200</p>	<p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture 	<p>Use</p> <ul style="list-style-type: none"> ■ Treats frequent heartburn (occurs 2 or more days a week). ■ Not intended for immediate relief of heartburn, this drug may take 1 to 4 days for full effect. 	<p>Active Ingredient</p> <p>(in each tablet)</p> <p>Omeprazole 20 mg.....Add reducer</p>	<p>Drug Facts</p> <p>Warning</p> <p>This label does not contain full product information. See carton for complete information. Heartburns may be recurrent or chronic. Use with caution in children.</p>	<p>NOT FOR RESALE</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week!</p> <p>Omeprazole Delayed Release Tablets 20 mg</p> <p>Acid Reducer</p> <p>14 Tablets One 14-day course of treatment</p> 	<p>Manufactured by: AbbVie Technologies, Ltd. 10 Halstead Street, Wiesbaden 2635200, Israel</p> <p>Made in Israel</p>	<p>CODE AREA</p> <p>• no varnish • no color</p> <p>: 915D5 FA F&</p>
	<p>Location for lot number and expiration date</p>						

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
- HAIRLINES: 0.5 pt

**Proposed Draft Labeling
 NDA 22-032
 Omeprazole Delayed Release Tablets, 20 mg
 14 Tablets (Inner Carton)**

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 ■ heartburn with light-headedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, swelling, or pain spreading to arms, neck or shoulders; or high blood pressure ■ frequent chest pain These may be signs of a serious condition. See your doctor.
Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours	Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ frequent weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or clostazolil (blood-thinning medicines) ■ prescription anti-fungal or anti-yeast medicines ■ prescription (and/or over-the-counter) diuretics (water pills) ■ prescription anti-retroviral medicines (medicines for HIV infection) ■ methotrexate (anti-rheumatoid medicine)
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).	Do not use if you are allergic to omeprazole ■ allergic to omeprazole or any of the other ingredients in this medicine
Other Information ■ read the directions on 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? 1-800-779-2650
Inactive Ingredients yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate	Stop 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 you are pregnant, nursing, or taking other medicines, ask your doctor before use.

Batch No.
EXP
01574 00 V2

CODE AREA

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

NOT FOR RESALE

Made in Israel
 Manufactured by:
Dexel Pharm 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

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

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

Compare to Prilosec OTC[®]*

DIE CUT WINDOW

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

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

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

CODE AREA

015D5 FA C10

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

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

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

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

Location for lot number and expiration date

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

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



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

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

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

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

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

FDA Approved Compare to Prilosec OTC®*

DIE CUT WINDOW

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

NDC 0000-000-00

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

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

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CODE AREA

915D5 FA C5-F

Location for lot number and expiration date

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

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

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

Questions or comments? 1-800-719-9260

Inactive ingredients
camphor wax, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, hydroxypropyl starch glycolate, sodium stearate, sodium starch glycolate, titanium dioxide, triethyl citrate.

Location for lot number and expiration date

Omeprazole Delayed Release Tablets 20mg

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet).....Omeprazole 20 mg.....Acid reducer</p> <p>Purpose</p> <p>Use</p> <p>■ Treats frequent heartburn (occurs 2 or more days a week)</p> <p>■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have</p> <ul style="list-style-type: none"> ■ back stools ■ heartburn with light-headedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating ■ pain spreading to arms, neck or shoulders, or lightheadedness <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ head heartburn over 3 months. This may be a sign of a more serious condition. ■ recent wheezing, paroxysmal cough or 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, dipyridol or clostazolol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ dexamethasone (steroid medicine) ■ tacrolimus or cyclosporine (immunosuppressant medicines) ■ prescription antiretroviral medicines for HIV infection ■ methoxybetaxolol (heart medicine) 	<p>Directions</p> <p>For adults 18 years of age and older</p> <ul style="list-style-type: none"> ■ 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, so many 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. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture
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CODE AREA

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

91530 FA C16



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

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

Compare to Prilosec OTC®*

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 Tablets

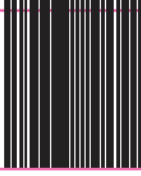
Two 14-day courses of treatment

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
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

Proposed Draft 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 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

Drug Facts (continued)

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

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

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

NDC 0000-000-00

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg
Acid Reducer



28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

Compare to Prilosec OTC®*

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

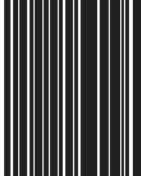
- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

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

Ask a doctor before use if you have:

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

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

CODE AREA

915D6 FA C10

Location for lot number and expiration date

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

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

Omeprazole Delayed Release Tablets 20mg

CODE AREA

91530 FA C5-F

Drug Facts (continued)

Warnings

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with high fevers, sweating or dizziness
- chest pain or shoulder pain with shortness of breath or sweating
- pain spreading to arms, neck or shoulders; or if light the address
- Ask a doctor before use if you have:
- had heartburn over 3 months. This may be a sign of a more serious condition.
- Ask a doctor before use if you are taking:
- clozapine (anxiety medicine)
- diazepam (anxiety medicine)
- dicyclanil or mycoprogolol (stomach medicine)
- tacrolimus or cyclosporin (immunosuppressant medicine)
- prescription anti-retroviral (medicines for HIV infection)
- methotrexate (arthritis medicine)

Use

■ Treats frequent heartburn (courses 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

Purpose

Omeprazole 20 mg.....acid reducer

Drug Facts (continued)

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- 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 or crush tablets.
- Repeat 14-Day Courses if needed
- you may repeat a 14-day course every 4 months
- do not take more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

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

Questions or comments? 1-800-719-9260

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

Drug Facts

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

Omeprazole 20 mg

Use

- Treats frequent heartburn (courses 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

Purpose

Omeprazole 20 mg.....acid reducer

Drug Facts (continued)

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- 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 or crush tablets.
- Repeat 14-Day Courses if needed
- you may repeat a 14-day course every 4 months
- do not take more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

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

Questions or comments? 1-800-719-9260

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

Omeprazole Delayed Release Tablets 20mg

28 Tablets

Two 14-day courses of treatment

Acid Reducer


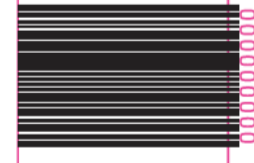
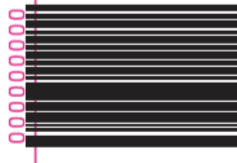

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

FDA Approved

Compare to Prilosec OTC®*

NDC 00000-000-00

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

Reference ID: 4179522

7-10-17

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

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



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

Drug Facts (continued)
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

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

Questions or comments? 1-800-719-9260

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

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 **Compare to Prilosec OTC***

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

00-0000-0000-000

Drug Facts
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

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

Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with **lightheadedness, sweating or dizziness**
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent **chest pain**
 These may be signs of a serious condition. See your doctor.

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

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



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

CODE AREA

915D6 FA C5-F

Location for lot number and expiration date

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

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

Omeprazole Delayed
Release Tablets 20 mg

CODE AREA

Drug Facts (continued)

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

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

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

Do not use if you have
 ■ chest pain or shortness of breath
 ■ chest pain or shortness of breath with sweating
 ■ pain spreading to arms, neck or shoulders, or light-headedness
 ■ recent chest pain
 ■ recent heartburn over 3 months. This may be a sign of a more serious condition

Ask a doctor before use if you have:
 ■ 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 clostazid (blood-thinning medicines)
 ■ azepam (anxiety medicine)
 ■ diazepam (heart medicine)
 ■ tacrolimus or cyclosporine (immunosuppressant medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ methotrexate (cancer medicine)

■ prescription antifungal or HIV infection
 ■ prescription antiretroviral (HIV infection)

Drug Facts

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

Directions
 ■ 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 or crush tablets.
 ■ Repeat 14-Day Courses if needed
 ■ you may repeat a 14-day course every 4 months
 ■ do not take more than 14 days or more often than every 4 months unless directed by a doctor

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

Omeprazole Delayed Release Tablets 20mg

28 Tablets

Two 14-day courses of treatment

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
 ■ you get dizziness
 ■ you get dizziness, 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
 Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have
 ■ chest pain or shortness of breath
 ■ chest pain or shortness of breath with sweating
 ■ pain spreading to arms, neck or shoulders, or light-headedness
 ■ recent chest pain
 ■ recent heartburn over 3 months. This may be a sign of a more serious condition

Ask a doctor before use if you have:
 ■ 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 clostazid (blood-thinning medicines)
 ■ azepam (anxiety medicine)
 ■ diazepam (heart medicine)
 ■ tacrolimus or cyclosporine (immunosuppressant medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ methotrexate (cancer medicine)

■ prescription antifungal or HIV infection
 ■ prescription antiretroviral (HIV infection)

Omeprazole Delayed Release Tablets 20mg

28 Tablets

Two 14-day courses of treatment

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
 ■ chest pain or shortness of breath
 ■ chest pain or shortness of breath with sweating
 ■ pain spreading to arms, neck or shoulders, or light-headedness
 ■ recent chest pain
 ■ recent heartburn over 3 months. This may be a sign of a more serious condition

Ask a doctor before use if you have:
 ■ 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 clostazid (blood-thinning medicines)
 ■ azepam (anxiety medicine)
 ■ diazepam (heart medicine)
 ■ tacrolimus or cyclosporine (immunosuppressant medicines)
 ■ prescription antifungal or anti-yeast medicines
 ■ methotrexate (cancer medicine)

■ prescription antifungal or HIV infection
 ■ prescription antiretroviral (HIV infection)

Drug Facts

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

Directions
 ■ 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 or crush tablets.
 ■ Repeat 14-Day Courses if needed
 ■ you may repeat a 14-day course every 4 months
 ■ do not take more than 14 days or more often than every 4 months unless directed by a doctor

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

Omeprazole Delayed Release Tablets 20mg

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 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

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



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

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 (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

Drug Facts (continued)

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

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

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 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
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain**

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

Ask a doctor before use if you have:

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



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

CODE AREA

915D6 FA C5-B

Location for lot number and expiration date

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

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

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

Questions or comments? 1-800-719-9280

Inactive ingredients (continued)
carruba wax, ferric oxide red, ferrous oxide, hydroxypropyl methylcellulose, hypromellose, hypromellose acetate succinate, lactose monohydrate, titanium dioxide, triethyl citrate.

Location for lot number and expiration date

Omeprazole Delayed
Release Tablets 20mg

<p>Drug Facts (continued)</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) ● 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 have: ● trouble or pain swallowing food, vomiting with blood, or bloody or black stools ● heartburn with high blood pressure, swelling or dizziness ● chest pain or shoulder pain with shortness of breath, sweating, or pain spreading to arms, neck or shoulders, or light-headedness ● recent chest pain These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: ● had heartburn over 3 months. This may be a sign of a more serious condition. ● frequent wheezing, particularly with heartburn ● unexplained weight loss ● nausea or vomiting ● stomach pain Ask a doctor or pharmacist before use if you are taking: ● warfarin, clopidogrel or clostazolol (blood-thinning medicines) ● proton pump inhibitors or anti-fungal medicines ● diazepam (anxiety medicine) ● digoxin (heart medicine) ● tacrolimus or cyclosporine (immunosuppressant medicines) ● proton pump inhibitors (medicines for H₂N refluxion) ● methotrexate (cancer medicine)</p> <p>Other information ● Read the directions and warnings before use. ● Keep the carton, 11 tablets important information. ● Store at 20-25°C (68-77°F) and protect from moisture.</p>	<p>Directions ● For adults 18 years of age and older: ● This product is to be used once a day (every 24 hours), every day for 14 days. ● It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours. ● 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. ● Repeat 14-Day Courses (if needed): ● You may repeat a 14-day course every 4 months. ● Do not take for more than 14 days or more often than every 4 months unless directed by a doctor. ● Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ● Read the directions and warnings before use. ● Keep the carton, 11 tablets important information. ● Store at 20-25°C (68-77°F) and protect from moisture.</p>
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CODE AREA

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

01530 FA C5-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 Compare to Prilosec OTC^{®*}

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

NDC 00000-000-00

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 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

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



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

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

Compare to Prilosec OTC®*

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 ~~X~~ 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
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating, pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**

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

Ask a doctor before use if you have:

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

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

Drug Facts (continued)

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

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:
Cexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel



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

CODE AREA

915D6 FA C5-E

Location for lot number and expiration date

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

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

Location for lot number and expiration date

CODE AREA

91530 FA 05-D

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Halkina Street, Yokneam 2069000, Israel

This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.
Drug Facts (continued)
Inactive Ingredients
carboxamide, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, 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 (continued)
Active ingredient (in each tablet) Omeprazole 20 mg.
Purpose Acid reducer.
Use
● Treats frequent heartburn (more than 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.
● heartburn with lightheadedness, sweating or dizziness.
● chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness.
● frequent chest pain.
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
● had heartburn over 3 months. This may be a sign of a more serious condition.
● frequent wheezing, particularly with the return of heartburn or vomiting.
● unexplained weight loss.
● nausea or vomiting.
● stomach pain.
Ask a doctor or pharmacist before use if you are taking:
● warfarin, clopidogrel or clopidogrel (blood-thinning medicines).
● prescription antifungal or anti-yeast medicines.
● diazepam (anxiety medicine).
● tacrolimus or mycophenolate mofetil (immune system medicines).
● prescription antidepressants (medicines for HIV infection).
● methotrexate (arthritis medicine).
Directions
● 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 for more than 14 days unless directed by your doctor.
● Swallow whole. Do not chew or crush tablets.
● Repeat 14-Day Courses if needed:
● You may repeat a 14-day course every 4 months.
● Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.
● Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
Other information
● Read the directions and warnings before use.
● Keep the carton. It contains important information.
● Store at 20-25°C (68-77°F) and protect from moisture.

Omeprazole Delayed Release Tablets 20 mg



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 Compare to Prilosec OTC®*

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

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 ~~14~~ Tablets

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

STANDARD FORMAT
TYPE SIZES:
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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

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



Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking:

- warfarin, clopidogrel or clostrazol (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

Drug Facts (continued)
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

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

Bonus Pack! 14 Free Compare to Prilosec OTC®*

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

00-000-0000-0000

Drug Facts

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

Use

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

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

CODE AREA

915D6 FA C5-D

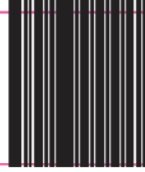
*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

STANDARD FORMAT

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 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

Proposed Draft 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.....Acid reducer

Purpose
Acid reducer

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

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

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with **lightheadedness, sweating or dizziness**
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
■ 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
carrauba 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

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

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**

NDC 0000-000-00

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg

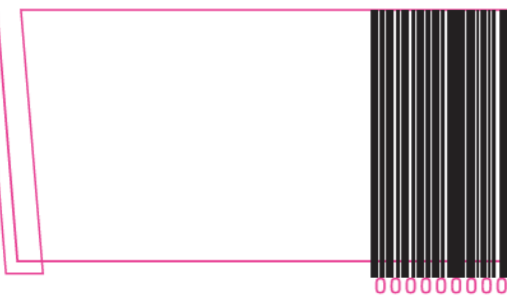
Acid Reducer

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



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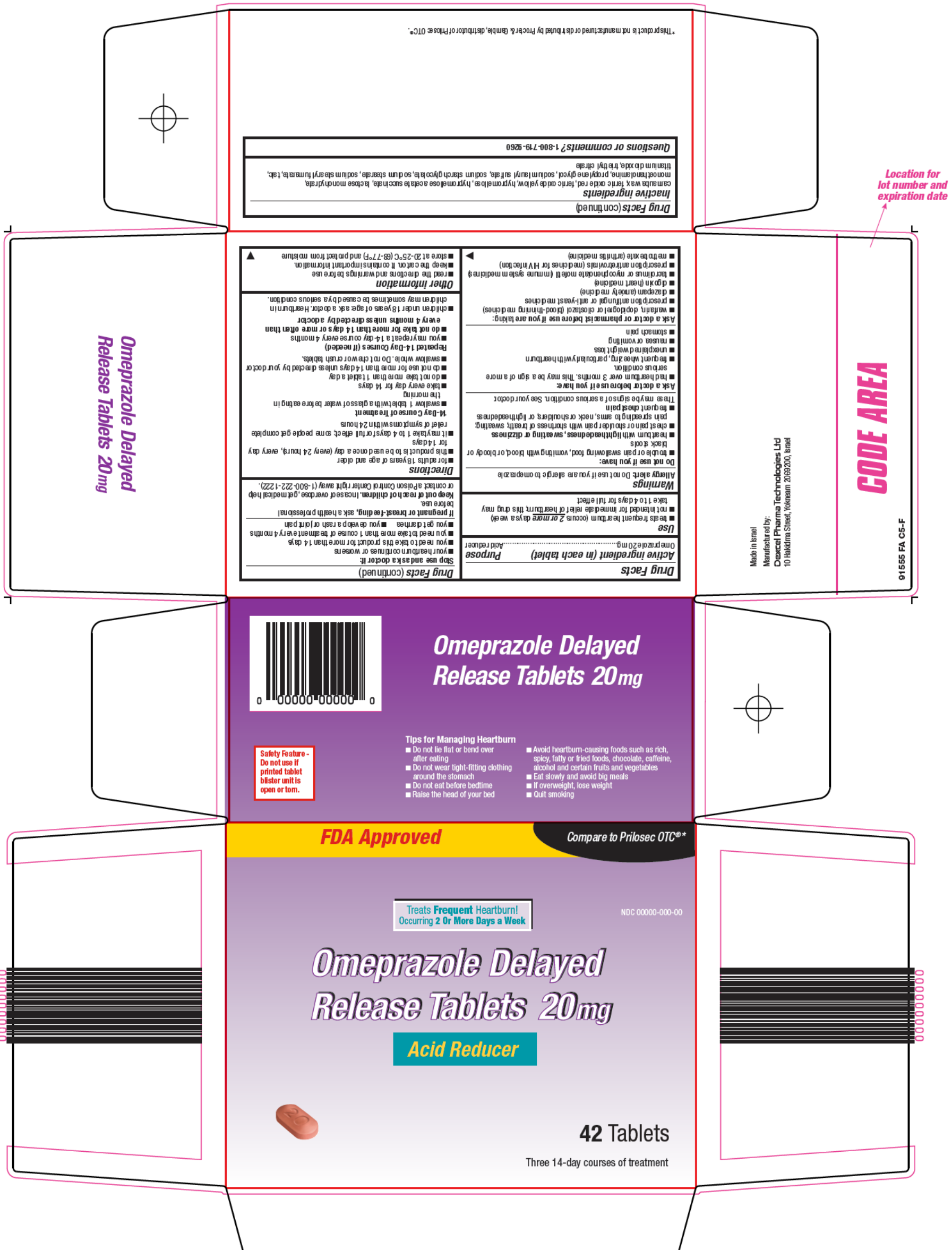
CODE AREA

915D7 FA C10

Location for lot number and expiration date

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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

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



Location for lot number and expiration date

CODE AREA

91555 FA C5-F

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakdama Street, Yokneam 208200, Israel

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

Questions or comments? 1-800-799-9260

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

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

Use
Do not use if you have:
● heartburn with high blood pressure, swelling or dizziness
● chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders or lightheadedness
● frequent chest pain
● frequent heartburn over 3 months. This may be a sign of a more serious condition.
● frequent wheezing, particularly with heartburn
● unexplained weight loss
● nausea or vomiting
● stomach pain

Warnings
Allergy alert: Do not use if you are allergic to omeprazole.
Do not use if you have:
● trouble or pain swallowing food, vomiting with blood or bloody or black stools
● heartburn with high blood pressure, swelling or dizziness
● chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders or lightheadedness
● frequent chest pain
● frequent heartburn over 3 months. This may be a sign of a more serious condition.
See your doctor.

Directions
● For adults 18 years of age and older:
● this product is to be used once a day (every 24 hours), every day for 14 days.
● It may take 1 to 4 days for full effect so 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 14 days unless directed by your doctor.
● Do not use for more than 14 days unless directed by your doctor.

Other information
● Repeated 14-Day Courses (if needed)
● You may repeat a 14-day course every 4 months 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 get diarrhea ● you develop a rash or joint pain
● you are pregnant or breast-feeding, ask a health professional before use.

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

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

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

Directions
● For adults 18 years of age and older:
● this product is to be used once a day (every 24 hours), every day for 14 days.
● It may take 1 to 4 days for full effect so 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 14 days unless directed by your doctor.
● Do not use for more than 14 days unless directed by your doctor.

Other information
● Repeated 14-Day Courses (if needed)
● You may repeat a 14-day course every 4 months 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 directions and warnings for use.
● Store at 20°-25°C (68°-77°F) and protect from moisture.



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

Compare to Prilosec OTC®*

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



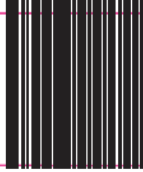
42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT
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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

Proposed Draft 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		Stop use and ask a doctor if:
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		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
<p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> trouble or pain swallowing food, vomiting with blood, or bloody or black stools heartburn with lightheadedness, sweating or dizziness chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness frequent chest pain <p>These may be signs of a serious condition. See your doctor.</p>		14-Day Course of Treatment
<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. frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain 		<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>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) 		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
		Other information
		<ul style="list-style-type: none"> children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F) and protect from moisture

Drug Facts (continued)

Inactive ingredients
 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

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE

CODE AREA

915D7 FA C5-F

NDC 0000-000-00

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

Location for lot number and expiration date

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

Proposed Draft 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) Purpose
 Omeprazole 20 mg.....Acid reducer

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

Compare to Prilosec OTC®*

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-0000-00

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

Omeprazole Delayed Release Tablets 20mg

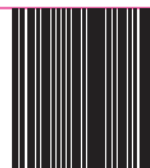
Acid Reducer

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE



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



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CODE AREA


915D7 FA C5-B

Location for lot number and expiration date

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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 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

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



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

Questions or comments? 1-800-719-9250

Inactive ingredients (continued)
cinnabar wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, mannitol, microcrystalline cellulose, polyethylene glycol, polyethylene glycol succinate, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide, triethyl citrate

Location for lot number and expiration date

Drug Facts (continued)

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

Use
Takes frequent heartburn (occurs 2 or more days a week) to 4 days for full effect
Do not intend 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
heartburn with lightheadedness, sweating or dizziness
chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
frequent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
had heartburn over 3 months, this may be a sign of a more serious condition.
frequent weight loss, 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 aspirin (blood-thinning medicines)
proton pump inhibitors (anti-acid medicines)
diazepam (anxiety medicine)
digoxin (heart medicine)
tacrolimus or cyclosporine (immunosuppressant medicines)
prescription antiarrhythmics (medicines for HIV infection)
methotrexate (anti-cancer 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

Drug Facts

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

Purpose
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).

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakdama Street, Yokneam 206200, Israel

91555 FA C5-C





NDC 00000-000-00

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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

CODE AREA

28 + 14 FREE

Compare to Prilosec OTC®*

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



42 Tablets

Three 14-day courses of treatment

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STANDARD FORMAT

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HAIRLINES: 0.5 pt

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

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Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg.....	Purpose Acid reducer	Stop use and ask a doctor if:	<ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ 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	Allergy alert: Do not use if you are allergic to omeprazole	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
Do not use if you have:	<ul style="list-style-type: none"> ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain 	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.
These may be signs of a serious condition. See your doctor.		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
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. ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain 	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
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) 		

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

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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

28 + 14 FREE

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

0 000000 000000 0

CODE AREA

915D7 FA C5-C

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

Location for lot number and expiration date


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

Omeprazole Delayed Release Tablets 20mg

Omeprazole Delayed Release Tablets 20mg



Omeprazole Delayed Release Tablets 20mg

CODE AREA

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg.....1 Active ingredient

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

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

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

Ask a doctor or pharmacist before use if you are taking:
● warfarin, clopidogrel or clostazol (blood-thinning medicines)
● prescription antiarrhythmic or anti-epileptic medicines
● digoxin (heart medicine)
● diazepam (anxiety medicine)
● prescription antiarrhythmic or anti-epileptic medicines
● methotrexate (anti-cancer medicine)

Other information
● children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
● every 4 months unless directed by a doctor
● do not take for more than 14 days or more often than you may repeat a 14-day course every 4 months
● 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 you may repeat a 14-day course every 4 months
● 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
● it may take 1 to 4 days for full effect; some people get complete relief within 1 to 4 days
● for adults 18 years of age and older
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Other information
● read the directions and warnings before use
● keep the carton, it contains important information.
● store at 20-25°C (68-77°F) and protect from moisture.

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg.....1 Active ingredient

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

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 stool
● heartburn with lightheadedness, sweating or dizziness
● chest pain or shoulder pain with shortness of breath; swelling; pain spreading to arms, neck or shoulders; or lightheadedness
● frequent chest pain
● frequent dizziness
● frequent weight loss
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● frequent stomach pain

Ask a doctor or pharmacist before use if you are taking:
● warfarin, clopidogrel or clostazol (blood-thinning medicines)
● prescription antiarrhythmic or anti-epileptic medicines
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Bonus! 14 Free Compare to Prilosec OTC®*

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

Drug Facts (continued)

Active ingredient (in each tablet)
Omeprazole 20 mg.....1 Active ingredient

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

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

Ask a doctor or pharmacist before use if you are taking:
● warfarin, clopidogrel or clostazol (blood-thinning medicines)
● prescription antiarrhythmic or anti-epileptic medicines
● digoxin (heart medicine)
● diazepam (anxiety medicine)
● prescription antiarrhythmic or anti-epileptic medicines
● methotrexate (anti-cancer medicine)

Other information
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● every 4 months unless directed by a doctor
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Drug Facts

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

Location for lot number and expiration date

01555 FA C5-E

Reference ID: 4179522

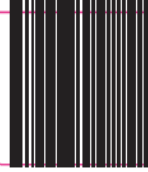
7-10-17

STANDARD FORMAT

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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

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

000000000



Drug Facts

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

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

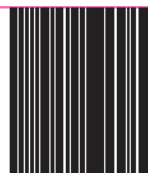
Acid Reducer

42 ~~28~~ Tablets



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

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



000000000



CODE AREA

915D7 FA C5-E

Location for lot number and expiration date

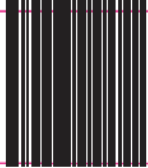
STANDARD FORMAT

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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

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

000000000



Drug Facts

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

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

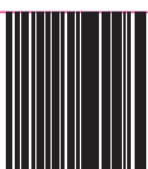
Acid Reducer

42 ~~28~~ Tablets



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

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



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CODE AREA

915D7 FA C5-D

Location for lot number and expiration date

STANDARD FORMAT

TYPE SIZES:
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 LEADING: 6.5 pt
 BULLETS: 5 pt Square with 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

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

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

Drug Facts (continued)

Inactive Ingredients
carrolla wax, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, lactose monohydrate, mannitol, polyethylene glycol, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

Location for lot number and expiration date

Omeprazole Delayed Release Tablets 20mg

Drug Facts

Active ingredient (in each tablet)
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
heartburn with nighttime awakenings, sweating or dizziness
chest pain or shoulder pain with shortness of breath, swelling, pain spreading to arms, neck or shoulders, or high blood pressure
frequent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
had heartburn over 3 months. This may be a sign of a more serious condition.
frequent wheezing, particularly with heartburn
unexplained weight loss
nausea or vomiting
stomach pain
Ask a doctor or pharmacist before use if you are taking:
warfarin, clopidogrel or clostazolam (blood-thinning medicines)
prescription antifungal or anti-yeast medicines
diazepam (anxiety medicine)
digoxin (heart medicine)
tacrolimus or mycophenolate mofetil (immune system medicines)
prescription anti-nausea drugs (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 or more often than you may repeat a 14-day course every 4 months.
Do not take for more than 14 days or more often than directed by a doctor.
Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition every 4 months unless directed by a doctor.

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.

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

CODE AREA

91555 FA C5-G

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

Triple Pack Three 14-day courses of treatment

Compare to Prilosec OTC®*

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



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



STANDARD FORMAT

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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

Proposed Draft 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
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

CODE AREA

915D7 FA C5-G

NDC 0000-000-00

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

Location for lot number and expiration date

STANDARD FORMAT

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

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

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Drug Facts

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

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

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

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
■ 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

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:
Cexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

0 000000 000000 0

CODE AREA

915D7 FA C5-A

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

Location for lot number and expiration date

STANDARD FORMAT

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

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

Drug Facts (continued)

Directions
For adults 18 years of age and older
Take 1 tablet with a glass of water before eating in the morning.
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.
Do not take more than 14 days unless directed by your doctor.
Do not take more than 14 days unless directed by your doctor.
Do not take more than 14 days unless directed by your doctor.
Do not take more than 14 days unless directed by your doctor.

Warnings
Do not use if you are allergic to omeprazole.
Do not use if you are allergic to omeprazole.
Do not use if you are allergic to omeprazole.
Do not use if you are allergic to omeprazole.
Do not use if you are allergic to omeprazole.

Use
Take the greatest heartburn relief occurs 2 or more days a week.
Not intended for immediate relief of heartburn. (This drug may take 1 to 4 days for full effect.)

Active ingredient (in each tablet)
Omeprazole 20 mg.
Inert ingredients: lactose, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, ferric oxide, and yellow iron oxide.

Other information
Keep this and all other medicines out of the reach of children. This may be a sign of a more serious condition.
Headache, dizziness, and weight loss.
Headache, dizziness, and weight loss.
Headache, dizziness, and weight loss.
Headache, dizziness, and weight loss.
Headache, dizziness, and weight loss.

Inactive ingredients
Inactive ingredients include: croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, ferric oxide, and yellow iron oxide.

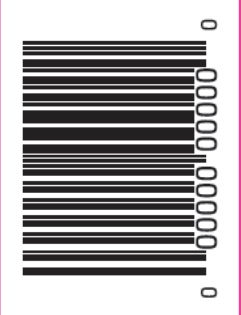
Questions or comments? 1-800-719-9250

Tips for Managing Heartburn
Do not eat or drink anything within 30 minutes of bedtime.
Do not eat or drink anything within 30 minutes of bedtime.
Do not eat or drink anything within 30 minutes of bedtime.
Do not eat or drink anything within 30 minutes of bedtime.
Do not eat or drink anything within 30 minutes of bedtime.

Manufactured by
Cipla Pharmaceuticals Ltd
108 Adams Street, Wixom, MI 48196-1000, USA

Made in Israel

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



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

Value Pack!
3-14 Tablet Cartons

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

Compare to Prilosec OTC®*

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



42 Tablets

Three 14-day courses of treatment

NDC 00000-000-00

STANDARD FORMAT
TYPE SIZES:
TITLE: 10 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
CONTINUOUS: 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: 6.7 pt
BULLETS: 5 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

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

000000000

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

000000000

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

Value Pack!
3-14 Tablet Bottles

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

CODE AREA

015D7 FA C5-J

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

Location for lot number and expiration date

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

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

Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel
Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel
Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	See low 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 X2	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel
Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel
Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel	Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer Push tablet through foil. Decel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel

Location for lot number and expiration date

= No Print Area

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

<p>Questions? 1-800-71-9280</p>	<p>Other information</p> <ul style="list-style-type: none"> read the directions and warnings before use keep the carton, it contains important information, store at 25°C (77°F) and protect from moisture 	<p>Drug Facts</p> <p>Active ingredient (on each tablet) Omeprazole 20 mg..... Add reducer</p>	<p>Use</p> <ul style="list-style-type: none"> Treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn, this drug may take 1 to 4 days for full effect 	<p>Safety Feature - Don't reuse if printed seal under cap is broken or missing.</p> <p>This label does not contain full product information. See carton for complete information, heed warnings and other important information on the full carton for full details.</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>14 Tablets</p> <p>One 14-day course of treatment</p> <p>Created by Wildberry Mint Flavor</p> <p>Made in Israel</p> <p>CODE AREA * no varnish * no color : 40105 FA F2</p>
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Location for lot number and expiration date

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
 - HAIRLINES: 0.5 pt

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

Location for lot number and expiration date

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

Made in Israel
 Manufactured by:
Dexcel Pharma Technologies Ltd
 10 Hahadima Street, Yokneam 2089200, Israel

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

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg.</p> <p>Purpose Acid reducer.</p> <p>Use ■ Treats frequent heartburn (occurs 2 or more days a week) ■ 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: ■ heartburn with high blood pressure, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; swelling; pain spreading to arm, neck or shoulder; or light-headedness ■ frequent chest pain ■ These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ frequent weight gain, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or clostazemide (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ methotrexate (cancer medicine) ■ methotrexate (art. 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 breastfeeding, 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 ■ 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 take more than 14 days unless directed by your doctor</p> <p>Repeat 14-Day Courses (if needed) ■ You may repeat a 14-day course every 4 months or more often than every 4 months unless directed by a doctor ■ Do not take for more than 14 days or more often than 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 ■ Keep the carton, it contains important information. ■ Store at 20-25°C (68-77°F) and protect from moisture.</p> <p>Inactive ingredients benzyl alcohol, camphor, carmellose, FD&C Blue #2, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, menthol, polyethylene glycol 350, 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>

CODE AREA

40-174 FA C3



Omeprazole Delayed Release Tablets 20mg

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

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

Compare to Prilosec OTC®*

NDC 00000-000-00

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

Proposed Draft Labeling
NDA 22-032

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

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

Compare to Prilosec OTC®*

NDC 0000-000-00

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
One 14-day course of treatment
1 BOTTLE INSIDE

Coated with Wildberry Mint Flavor

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

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

CODE AREA
401D5 FA C3

Location for lot number and expiration date

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

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

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

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.

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

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

**Proposed Draft Labeling
 NDA 22-032**

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

Location for lot number and expiration date

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

Made in Israel
 Manufactured by:
Decelex Pharma Technologies Ltd
 10 Hahadima Street, Yokneam 2089200, Israel

*This product is not manufactured or distributed by Prilosec®/Esomeprazole, distributor of Prilosec OTC®.

<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 ■ For a delayed release tablet (every 24 hours), every day ■ 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</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 take more than 14 days unless directed by your doctor</p> <p>Repeat 14-Day Courses (if needed) ■ You may repeat a 14-day course every 4 months ■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor</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 benzyl alcohol, carnuba wax, hypromellose acetate succinate, lactose monohydrate, mannitol, modified starch, monobasic potassium phosphate, polyethylene glycol 350, sodium lauryl sulfate, potassium glycolate, sodium stearate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate</p> <p>FD&C Blue #2 hydrocarmin aluminum lake, iron hydroxide, iron oxide, yellow iron oxide</p>	<p>Warnings ■ Do not use if you are allergic to omeprazole ■ Do not use if you have: ■ Stomach pain ■ Vomiting with blood or bloody or black stools ■ Heartburn or pain swallowing food, vomiting with blood, or bloody or black stools ■ Stomach pain ■ Swelling of the face, lips, or tongue ■ Difficulty breathing ■ Dizziness ■ Headache ■ Blurred vision ■ Rash ■ Itching ■ Stomach pain ■ Stomach pain ■ Stomach pain ■ Stomach pain</p> <p>Use ■ This is the first 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>Directions ■ For a delayed release tablet (every 24 hours), every day ■ 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</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 take more than 14 days unless directed by your doctor</p> <p>Repeat 14-Day Courses (if needed) ■ You may repeat a 14-day course every 4 months ■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor</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 benzyl alcohol, carnuba wax, hypromellose acetate succinate, lactose monohydrate, mannitol, modified starch, monobasic potassium phosphate, polyethylene glycol 350, sodium lauryl sulfate, potassium glycolate, sodium stearate, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate</p> <p>FD&C Blue #2 hydrocarmin aluminum lake, iron hydroxide, iron oxide, yellow iron oxide</p>
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CODE AREA

40174 FA C5-F



Omeprazole Delayed Release Tablets 20mg

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

FDA Approved

Compare to Prilosec OTC®*

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

NDC 00000-000-00

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

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



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

FDA Approved Compare to Prilosec OTC®*

DIE CUT WINDOW

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

SWALLOW - DO NOT CHEW

14 Tablets



Coated with Wildberry Mint Flavor

One 14-day course of treatment
 1 BOTTLE INSIDE



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

CODE AREA

401D5 FA C3-F

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

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

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

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

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

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

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



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

Questions or comments? 1-800-719-9260

Location for lot number and expiration date

Omeprazole Delayed Release Tablets 20 mg

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
trouble or pain swallowing food, vomiting with blood, or bloody or black stools
heartburn with nighttime awakenings, swelling or dizziness
chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
urgent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
had heartburn over 3 months. This may be a sign of a more serious condition.
trouble or pain swallowing food, vomiting with blood, or bloody or black stools
heartburn with nighttime awakenings, swelling or dizziness
chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
urgent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor or pharmacist before use if you are taking:
warfarin, clopidogrel, or clopidogrel (blood-thinning medicines)
proton pump inhibitors (medicines for acid reflux)
antibiotics or mycoplasma medicine (immune system medicines)
lactation or mycoplasma medicine (immune system medicines)
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 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).

Directions
For adults 18 years of age and older (every 24 hours), every day for 14 days
It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
swallow 1 tablet with a glass of water before eating in the morning
take every day for 14 days
do not take more than 1 tablet a day
do not use for more than 14 days unless directed by your doctor
swallow whole. Do not chew, crush, or suck tablets.
Repeat 14-Day Courses if needed
you may repeat a 14-day course every 4 months
do not take 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
Keep the carbonit contains important information
store at 20-25°C (68-77°F) and protect from moisture

CODE AREA

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

40130 FA C3

Omeprazole Delayed Release Tablets 20mg



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

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

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

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

Compare to Prilosec OTC®*

NDC 00000-000-00

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: 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

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



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

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

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

FDA Approved **Compare to Prilosec OTC®***

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-0000-00

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
2 BOTTLES INSIDE

Coated with Wildberry Mint Flavor

0 00000 00000 0

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

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

Drug Facts (continued)

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

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? 1-800-719-9280

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

CODE AREA

401D6 FA C3-F

Location for lot number and expiration date

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

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



Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking:

- warfarin, clopidogrel or 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

Drug Facts (continued)
14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Other information

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

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

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

Compare to Prilosec OTC®*

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 Tablets

Coated with **Wildberry Mint Flavor**

Two 14-day courses of treatment
2 BOTTLES INSIDE

CODE AREA

401D6 FA C3-B

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

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
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

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

Omeprazole Delayed Release Tablets 20mg

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

<p>Drug Facts (continued)</p> <p>Inactive Ingredients sucryl alcohol, camphor, camphor wax, FD&C Blue #2, indigo carmine aluminum lake, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium steryl fumarate, sucrose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9280</p>	<p>Other Information</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>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions</p> <p>For adults 18 years of age and older</p> <p>Take 1 tablet with a glass of water before eating in the morning.</p> <p>Take every day for 14 days.</p> <p>Do not take more than 1 tablet a day.</p> <p>Do not take for more than 14 days unless directed by your doctor.</p> <p>Swallow whole. Do not chew, crush, or suck tablets.</p> <p>Repeat 14-Day Courses (if needed)</p> <p>You may repeat a 14-day course every 4 months.</p> <p>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>
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CODE AREA

40130 FA C5-E

Drug Facts

Use

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

Not intended for immediate relief of heartburn. (This drug may take 1 to 4 days for full effect)

Warnings

Do not use if you are allergic to omeprazole

Do not use if you have:

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

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.
- trouble swallowing, 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 clozapine (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- lithium (heart medicine)
- calcium or mycophenolate mofetil (immune system medicines)
- prescription antidepressants (medicines for HIV infection)
- methotrexate (cancer medicine)

Drug Facts (continued)

Active ingredient (in each tablet)

Omeprazole 20 mg.....Aid reader

Purpose

Acid reducer

Use

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

Not intended for immediate relief of heartburn. (This drug may take 1 to 4 days for full effect)

Warnings

Do not use if you are allergic to omeprazole

Do not use if you have:

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

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.
- trouble swallowing, 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 clozapine (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- lithium (heart medicine)
- calcium or mycophenolate mofetil (immune system medicines)
- prescription antidepressants (medicines for HIV infection)
- methotrexate (cancer medicine)

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

Compare to Prilosec OTC®*

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

NDC 00000-000-00

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

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

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



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

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



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

Bonus Pack! 14 Free Compare to Prilosec OTC*

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 Tablets



Coated with Wildberry Mint Flavor

Two 14-day courses of treatment
2 BOTTLES INSIDE



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

CODE AREA

401D6 FA C3-D

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

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.

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? 1-800-719-9280

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

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

Omeprazole Delayed
Release Tablets 20 mg

Drug Facts (continued)

Warnings

Do not use if you have:

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

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

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

■ Do not use if you have:

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

Other information

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

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
- 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

- 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.

Active ingredient (in each tablet)

Omeprazole 20 mg.....Acid reducer

Use

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

Warnings

Do not use if you have:

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

Other information

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

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
- 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


- 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.

Active ingredient (in each tablet)

Omeprazole 20 mg.....Acid reducer

CODE AREA

Omeprazole Delayed Release Tablets 20mg



0 000000 000000 0

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

Tips for Managing Heartburn

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

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


Compare to Prilosec OTC[®]*

NDC 00000-000-00

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 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

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

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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking: ■ 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:
Dexel Pharma Technologies Ltd
 10 Hakidma Street, Yokneam 2069200, Israel

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

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**

NDC 0000-000-00

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

0 000000 000000 0

CODE AREA

40174 FA C3

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

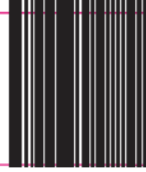
Location for lot number and expiration date

STANDARD FORMAT

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 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
 TEXT: 6 pt Helvetica Neue 57 Condensed
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 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

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

000000000



Drug Facts

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

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 00000-000-00

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE



Coated with Wildberry Mint Flavor

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



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CODE AREA

40174 FA C3-F

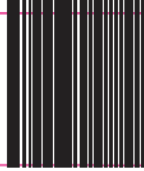
Location for lot number and expiration date

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 HAIRLINES: 0.5 pt

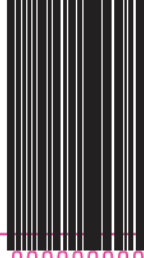
Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg		Purpose Acid reducer	
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		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).	
Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor.		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.	
Ask a doctor before use if you have: ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain		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	
Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or clobazepam (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)		Questions or comments? 1-800-719-9260	

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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

Compare to Prilosec OTC®*

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

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Coated with Wildberry Mint Flavor

0 00000 00000 0

CODE AREA

40174 FA C3-B


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

STANDARD FORMAT

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

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

Omeprazole Delayed
Release Tablets 20mg



**Omeprazole Delayed
Release Tablets 20mg**

40155 FA C5-C

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

Compare to Prilosec OTC[®]*


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

NDC 00000-000-00

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment

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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 have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or light-headedness
■ frequent chest pain
■ frequent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain
Ask a doctor or pharmacist before use if you are taking:
■ warfarin, clopidogrel or clozapine (blood-thinning medicines)
■ prescription antifungal or anti-fungal medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ calcium or mycophenolate mofetil (immune system medicines)
■ prescription anti-infectives (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
■ 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
■ 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.
■ Do not take for more than 14 days or more often than every 4 months unless directed by your doctor.
■ Swallow whole. Do not chew, crush, or suck tablets.
■ Do not use for more than 14 days unless directed by your doctor.
■ Take every day for 14 days.
■ Take every day for 14 days.
■ Swallow 1 tablet with a glass of water before eating in the morning.
■ These may be signs of a serious condition. See your doctor.

Questions or comments? 1-800-719-9200

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

Location for lot number and expiration date

CODE AREA

Made in Israel
Manufactured by:
Develco Pharma Technologies Ltd
10 Hakdama Street, Yotvata 2069001, Israel

STANDARD FORMAT

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

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

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 ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or clobazam (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 *This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.*	

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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

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

Coated with **Wildberry Mint Flavor**

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

0 00000 00000 0

CODE AREA

40174 FA C3-C

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

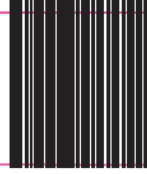
Location for lot number and expiration date

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SUBHEADINGS: 6 pt Helvetica Neue 77 Bold 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

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

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Tips for Managing Heartburn

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

Drug Facts

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

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

Warnings

Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with **lightheadedness, sweating or dizziness**
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent **chest pain**
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ 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

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

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

Bonus! 14 Free

Compare to Prilosec OTC®*

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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

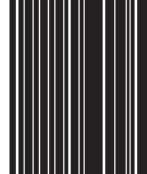
Three ~~Two~~ 14-day courses of treatment
 3 ~~2~~ BOTTLES INSIDE

Coated with **Wildberry Mint Flavor**



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

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CODE AREA


40174 FA C3-E

Location for lot number and expiration date

STANDARD FORMAT

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 HAIRLINES: 0.5 pt

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



*This product is not manufactured or distributed by Procter & Gamble, distributor of these OTC's.

<p>Drug Facts (continued)</p> <p>Inactive ingredients benzyl alcohol, camphor, carnuba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate, starch glycolate, sodium stearate, sodium steryl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? 1-800-719-9260</p>	<p>Drug Facts (continued)</p> <p>Warnings Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Use Do not use if you have: - trouble or pain swallowing food, vomiting with blood, or bloody or black stools - heartburn with high blood pressure, swelling or dizziness - chest pain or shoulder pain with shortness of breath, sweating, fainting, or lightheadedness - frequent chest pain - frequent wheezing, particularly with heartburn - unexplained weight loss - nausea or vomiting - stomach pain</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. - frequent wheezing, particularly with heartburn - trouble or pain swallowing food, vomiting with blood, or bloody or black stools - heartburn with high blood pressure, swelling or dizziness - chest pain or shoulder pain with shortness of breath, sweating, fainting, or lightheadedness - frequent chest pain - frequent wheezing, particularly with heartburn - trouble or pain swallowing food, vomiting with blood, or bloody or black stools</p> <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you are taking: - warfarin, daptomycin, or clozapine (blood-thinning medicines) - prescription antifungal or anti-yeast medicines - dexamethasone (steroid medicine) - digoxin (heart medicine) - tacrolimus or cyclosporine (immunosuppressive medicines) - baclofen or myoclonic muscle relaxants for HIV infection - methotrexate (arthritis medicine)</p>
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Location for lot number and expiration date

CODE AREA

40155 FA CS-D

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





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



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

NDC 00000-000-00

42 ~~28~~ Tablets

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

Coated with Wildberry Mint Flavor





Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

NDC 00000-000-00

42 ~~28~~ Tablets

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

Coated with Wildberry Mint Flavor





Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

NDC 00000-000-00

42 ~~28~~ Tablets

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

Coated with Wildberry Mint Flavor

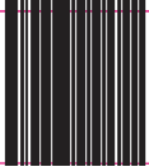


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Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets (Bottle Carton)

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

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

- 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 Compare to Prilosec OTC®*

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

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

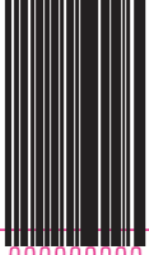
Acid Reducer
 SWALLOW - DO NOT CHEW


 Coated with Wildberry Mint Flavor

42~~28~~ Tablets
 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

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CODE AREA

40174 FA C3-D

Location for lot number and expiration date

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HEAVY LINES: 1.5 pt
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Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg (Wildberry Mint)
42 Tablets



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<p style="font-size: x-small; text-align: center;">Drug Facts (continued)</p> <p style="font-size: x-small;">Inactive ingredients FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate, sodium starch glycolate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p>	<p style="font-size: x-small; text-align: center;">Questions or comments? 1-800-719-9250</p>
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Location for lot number and expiration date


Omeprazole Delayed
Release Tablets 20mg

<p style="font-size: x-small;">Drug Facts</p> <p style="font-size: x-small;">Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</p> <p style="font-size: x-small;">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 style="font-size: x-small;">Warnings Allergy alert: Do not use if you are allergic to omeprazole</p> <p style="font-size: x-small;">Do not use if you have: ● trouble or pain swallowing food, vomiting with blood, or bloody or black stools ● heartburn with lightheadedness, weakness or dizziness ● chest pain or shoulder pain with shortness of breath; swelling; pain spreading to arms, neck or shoulders; or lightheadedness</p> <p style="font-size: x-small;">● frequent weight loss ● unexplained weight loss ● nausea or vomiting ● stomach pain</p> <p style="font-size: x-small;">Ask a doctor before use if you are taking: ● warfarin, clopidogrel or clostazolol (blood-thinning medicines) ● prescription anti-fungal or anti-yeast medicines ● dexamethasone (steroid medicine) ● tacrolimus or cyclosporin (immunosuppressant medicines) ● prescription anti-arrhythmia medicines (medicines for heart rhythm) ● methotrexate (anti-cancer medicine)</p>	<p style="font-size: x-small;">Other information</p> <p style="font-size: x-small;">● 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 style="font-size: x-small;">Directions</p> <p style="font-size: x-small;">● for adults 18 years of age and older ● this product is to be used once a day every 24 hours, every day for 14 days ● it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</p> <p style="font-size: x-small;">14-Day Course of Treatment</p> <p style="font-size: x-small;">● swallow 1 tablet with a glass of water before eating in the morning ● take every day for 14 days ● do not take more than 14 days unless directed by your doctor ● do not take more than 14 days unless directed by your doctor</p> <p style="font-size: x-small;">Repeated 14-Day Courses (if needed)</p> <p style="font-size: x-small;">● 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</p> <p style="font-size: x-small;">● children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>
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CODE AREA

40155 FA C5-G






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
- 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
- Do not eat before bedtime
- If overweight, lose weight
- Raise the head of your bed
- Quit smoking



Triple Pack

Three 14-day courses of treatment


Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

NDC 00000-000-00

Omeprazole Delayed
Release Tablets 20mg

Acid Reducer


SWALLOW - DO NOT CHEW





Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment








Omeprazole Delayed
Release Tablets 20mg

Acid Reducer


SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

42 Tablets

Three 14-day courses of treatment



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

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

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

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

Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with lightheadedness, sweating or dizziness
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 These may be signs of a serious condition. See your doctor.

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

Ask a doctor or pharmacist before use if you are taking:
 ■ warfarin, clopidogrel or clobazepam (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
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Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
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■ 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

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

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

Compare to Prilosec OTC*[†]

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

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Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE

Coated with Wildberry Mint Flavor

40174 FA C3-G

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



CODE AREA

Location for lot number and expiration date

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

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Drug Facts		Drug Facts (continued)
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer	Stop use and ask a doctor if: ■ 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 ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor.	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. ■ 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, 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
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)		Questions or comments? 1-800-719-9260

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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

3 PACK Three 14-day courses of treatment

Compare to Prilosec OTC*

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

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer
 SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
 3 BOTTLES INSIDE

Coated with Wildberry Mint Flavor

40174 FA C3-A

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



CODE AREA

Location for lot number and expiration date

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

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



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<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose 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</p> <p>Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor.</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. ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)</p>	<p>Drug Facts (continued)</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. 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 ■ 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 ■ swallow whole. Do not chew, crush, or suck tablets.</p> <p>Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ 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>Drug Facts (continued)</p> <p>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</p> <p>Questions or comments? 1-800-719-9260</p> <p>Made in Israel Manufactured by: Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p> <p><small>*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC*.</small></p>	<div style="text-align: center;">  </div> <div style="text-align: center; border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Safety Feature - Do not use if printed seal under cap is broken or missing</p> </div>
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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.
current labeling information, please visit <https://www.fda.gov/drugs>

Proposed Draft Labeling
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg
14 Tablets Peel Off Coupon

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 00000-000-00

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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



14 Tablets

91574 FA CP4

One 14-day course of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCI, PO Box 880036, El Paso, TX 88988-0036

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.



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

Reference ID: 4179522

8-10-17

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

Instant Redeemable Coupon - Expires XX/XX/XX

peel off coupon

SAVE \$X NOW!
On This Purchase

NDC 0000-000-00

Compare to Prilosec OTC**

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

915D5 FA CP4

Reference ID: 4179522



BACK PANEL

SAVE \$X NOW!

Omeprazole Delayed Release Tablets 20 mg 14 Count

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemed for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCR, PO Box 880036, El Paso, TX 88528-0036



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8-10-17

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

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
28 Tablets Peel Off Coupon

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 00000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 Tablets

Two 14-day courses of treatment

91530 FA CP4

BACK PANEL

SAVE \$X NOW!


MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

Omeprazole Delayed Release Tablets 20 mg
28 Count

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.

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



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

Proposed Draft Labeling

NDA 22-032

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

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 0000-000-00

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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

28 Tablets



915D6 FA CP4

Two 14-day courses of treatment
2 BOTTLES INSIDE

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

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

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



0 00000 00000 0

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

Reference ID: 4179522

8-10-17

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

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
42 Tablets Peel Off Coupon

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 00000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



42 Tablets

Three 14-day courses of treatment

91555 FA CP4

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

Omeprazole Delayed Release Tablets 20 mg 42 Count

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.

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



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

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

FRONT PANEL

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

Prilosec
coupon

NDC 0000-000-00

Compare to Prilosec OTC®*

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
3 BOTTLES INSIDE

915D7 FA CP4



BACK PANEL

SAVE \$X NOW!

Omeprazole Delayed Release Tablets 20 mg 42 Count

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. **RETAILER:** This coupon will be redeemed for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to:
NCH, PO Box 880036
El Paso, TX 79958-0036

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



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Reference ID: 4179522

8-10-17

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

Proposed Draft Labeling

NDA 22-032

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

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

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

40174 FA CP3

One 14-day course of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
14 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

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

products (plus a handling
fee) if submitted in
compliance with the terms
of this offer. Cash value
1/100th of one cent. Limit
one coupon per customer.
Do Not Double. Coupon is
non-reproducible. Coupons
cannot be combined. Mail
properly handled coupons
to: NCH, PO Box 880036, El
Paso, TX 88588-0036

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.



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

Reference ID: 4179522

8-10-17

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

**Proposed Draft Labeling
NDA 22-032**

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

FRONT PANEL

Instant Redeemable Coupon - Expires XX/XX/XX
SAVE \$X NOW!
On This Purchase

post off
08/99/01

NDC 0000-0000-00

Compare to
Prilosec OTC[®]

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

Reference ID: 4179522 BOTTLE INSIDE



BACK PANEL

SAVE \$X NOW!

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

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

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

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



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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

Peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

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

40130 FA CP3

28 Tablets

Two 14-day courses of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) if submitted in compliance with the terms of this offer. Cash value 1/100th of one cent. Limit one coupon per customer. Do Not Double. Coupon is non-reproducible. Coupons cannot be combined. Mail properly handled coupons to: NCH, PO Box 880036, El Paso, TX 88988-0036

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.



Omeprazole Delayed Release Tablets 20 mg 28 Count

Reference ID: 4179522

8-10-17

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

Compare to Prilosec OTC®*

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 Tablets

Coated with
Wildberry Mint Flavor

Two 14-day courses of treatment
2 BOTTLES INSIDE

: 401DB FA CP3



BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

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

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



0 00000 00000 0

Reference ID: 4179522

Omeprazole Delayed Release Tablets 20 mg 28 Count

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

Peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!

On This Purchase

Compare to Prilosec OTC®*

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
40155 FA CP3

42 Tablets

Three 14-day courses of treatment

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
42 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

Omeprazole Delayed Release Tablets 20 mg 42 Count

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.

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



Reference ID: 4179522

8-10-17

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

FRONT PANEL

Deal of
the
month

Instant Redeemable Coupon - Expires XX/XX/XX

SAVE \$X NOW!
On This Purchase

NDC 0000-000-00

Compare to Prilosec OTC®*

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
3 BOTTLES INSIDE

: 401D7 FA CP3

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

on your purchase of
42 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

CONSUMER: Only one coupon is redeemable
per purchase. RETAILER: This coupon will
be redeemed for face value on specified
products (plus a handling fee) if submitted
in compliance with the
terms of this offer. Cash
value 1/100th of one cent.

Limit one coupon per
customer. Do Not Double.
Coupon is non-reproducible.
Coupons cannot be
combined. Mail properly
handled coupons to:

NIH, P.O. Box 885036,
El Paso, TX 88588-0036

COUPON NOT SUBJECT
TO DOUBLING

Customer pays any sales tax.



Omeprazole Delayed Release Tablets 20 mg 42 Count

Reference ID: 4179522

8-10-17