

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

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Push tablet through foil.
 Dexcel Pharma
 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

Omeprazole DR Tablets
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**Location for
 lot number and
 expiration date**

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

NOT FOR RESALE

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

Drug Facts

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

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

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

Questions? 1-800-719-9260

Manufactured by:
Cesariel Pharma Technologies Ltd
10 Hekima Street, Netanya 2266200, Israel
Made in Israel

CODE AREA
• no varnish • no color
: 915D5 FA F8

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

[illegible]

Batch No.
EXP
91574 00 V2

GODDE AREA

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

NOT FOR RESALE

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

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

Omeprazole

delayed release tablets 20 mg
acid reducer

14 TABLETS

One 14-day course of treatment



Tips for Managing Heartburn

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

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

MODIFIED FORMAT

TYPE SIZES:

TITLE 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

Location for
lot number and
expiration date

CODE AREA

91574 FA C16

Made in Israel
Manufactured by:
Deacel Pharma Technologies Ltd
10 Haddama Street, Yokneam 2089201, 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

Drug Facts Active ingredient (in each tablet) Omeprazole 20 mg... Purpose Acid reducer	
Warnings Do not use if you have: ■ 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, 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 ■ stomach pain Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel, or clostridium (blood-thinning medicines) ■ prescription antifungal or anti-viral (immune system medicines) ■ diazepam (anxiety medicine) ■ dexamethasone (heart medicine) ■ prescription antifungal or anti-viral (immune system medicines) ■ methotrexate (arthritis medicine) Stop use and ask a doctor if: ■ you have heartburn more often or worse than 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 breastfeeding, ask a health professional before use.	
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 cap on. It contains important information. ■ Store at 20-25°C (68-77°F) and protect from moisture Inactive ingredients carboxylic acid, ferrous fumarate, talc, titanium dioxide, triethylcitrate Questions or comments? 1-800-719-9260	



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



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
14 Tablets (Bottle Carton)



Drug Facts (continued)

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)

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

Questions or comments? 1-800-719-9260

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

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

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

CODE AREA

015D5 FA C10

**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

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

Omeprazole Delayed Release Tablets, 20 mg
14 Tablets

7-10-17

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

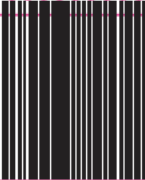


TYPE SIZES:
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TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
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HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt 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

4-25-17

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

000000000



Drug Facts (continued)

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

- warfarin, clopidogrel or cilestazol (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

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.....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

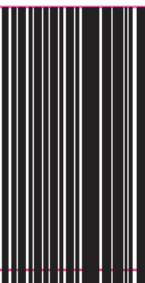
Do not use if you have:

- 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



000000000



*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

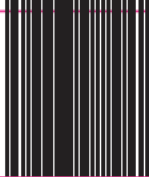
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

000000000



Drug Facts (continued)

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus 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.

Made in Israel

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

Tips for Managing Heartburn

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

FDA Approved

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



28 Tablets

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

915D6 FA C5-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

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

Drug Facts (continued)

Inactive Ingredients
carnauba wax, ferric oxide red, hypromellose, hydroxypropyl methylcellulose, hypromellose acetate succinate, lactose monohydrate, mannitol, polyethylene glycol, sodium lauryl sulfate, sodium stearate, sodium stearate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260

Location for
lot number and
expiration date

Drug Facts
Omeprazole 20 mg.....Acid reducer

Active ingredient (in each tablet)
Purpose

Use
■ treats frequent heartburn (course 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 blood 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 if 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 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)
■ dexamethasone (corticosteroid)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretroviral (medicines for HIV infection)
■ methotrexate (arthritis medicine)

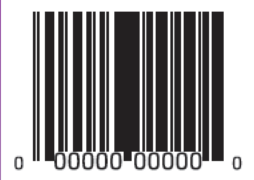
Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
■ do not take 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 (Repeat 14-day Courses if needed)
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew or crush tablets.
■ take every day for 14 days
■ 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)
■ dexamethasone (corticosteroid)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretroviral (medicines for HIV infection)
■ methotrexate (arthritis medicine)

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

CODE AREA

91530 FA CS-B

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



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

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

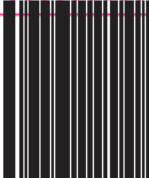
STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
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(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)

0000000000



Drug Facts (continued)

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)

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

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



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

CODE AREA

915D6 FA C5-B

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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

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

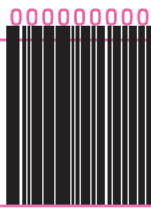
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TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

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

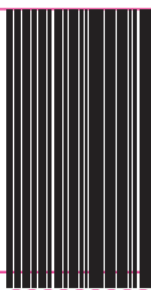
carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

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! 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



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

CODE AREA

915D6 FA C5-E

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

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 (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

Omeprazole Delayed Release Tablets, 20 mg 28 Tablets

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

Drug Facts (continued)

Inactive ingredients
 carnuba wax, ferric oxide red, titanium dioxide, triethyl citrate

carbamidax wax; ferric oxide yellow; hypromellose acetate sodium salt; lactose monohydrate; mannitol; polyethylene glycol; sodium lauryl sulfate; sodium stearate; sodium starch glycolate; sorbitol trihydrate

Questions or comments? 1-800-719-9260

**Location for
lot number and
expiration date**

CODE AREA

91530 FA C5-D

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

Omeprazole Delayed Release Tablets 20mg

▶ 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 your doctor before use if you are taking:

- warfarin, clopidogrel or clozapine (blood-thinning medicines)
- paracetamol, aspirin or other anti-inflammatory medicines
- dexamethasone (steroid medicine)
- diazepam (anxiety medicine)
- tacrolimus or mycophenolate (immunosuppressant medicines)
- metformin (for diabetes)
- mifepristone (abortion pills)

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

	take 1 to 4 days for full effect
--	----------------------------------

Use

- treats the frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may

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

Drug Facts

Other information

- this product is to be used once a day (every 24 hours), everyday for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
- 14-day Course of Treatment
 - swallow 1 tablet with a glass of water before getting into the morning
 - take every day for 14 days
 - do not take more than 1 tablet a day
 - use for more than 14 days unless directed by your doctor
 - swallow whole. Do not chew or crush tablets.
- Repeat a 14-day Course (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 for advice on how to use
- children may sometimes be caused by a serious condition
- store at 20-25°C (68-77°F) and protect from moisture
- keep the container tightly closed and keep it out of reach of children
- read the directions and warnings before use

Directions
 or contact a Poison Control Center right away (1-800-222-1222).

Keep out of reach of children. In case of overdose, get medical help

■ you get diarrhea ■ you develop a rash or joint pain

- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

Living Facts (continued)

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

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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

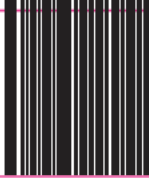
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HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 22-032
Omeprazole Delayed Release Tablets, 20 mg
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:
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 ~~1~~ BOTTLES INSIDE



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

CODE AREA

915D6 FA C5-D

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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

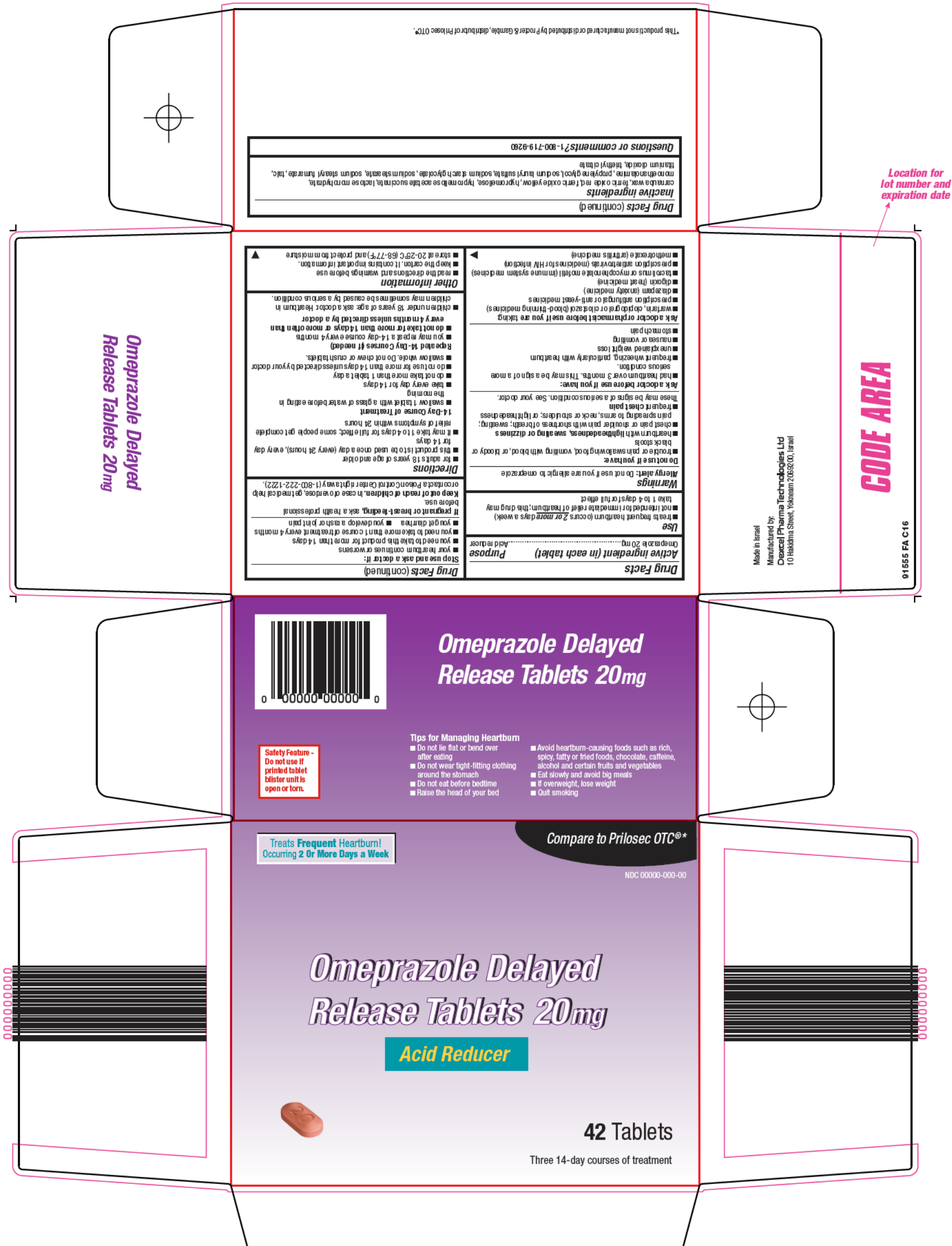
Location for lot number and expiration date

STANDARD FORMAT

TYPE SIZES:

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



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



STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

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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)

000000000

Drug Facts

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

Purpose

Use

Warnings

Ask a doctor before use if you have:

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

Stop use and ask a doctor if:

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

14-Day Course of Treatment

Repeated 14-Day Courses (if needed)

Other information

Drug Facts (continued)

Inactive ingredients

Questions or comments?

Made in Israel

Manufactured by:

10 Hakidma Street, Yokneam 2069200, Israel

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

Tips for Managing Heartburn

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

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

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

000000000000000000000000

CODE AREA

915D7 FA C5-F

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

Location for lot number and expiration date

Reference ID: 4179522

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

7-10-17

Proposed Draft Labeling NDA 22-032



91555 FA C5-B

Omeprazole Delayed Release Tablets 20 mg

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

- 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®*

NDC 00000-000-00

14 FREE

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment

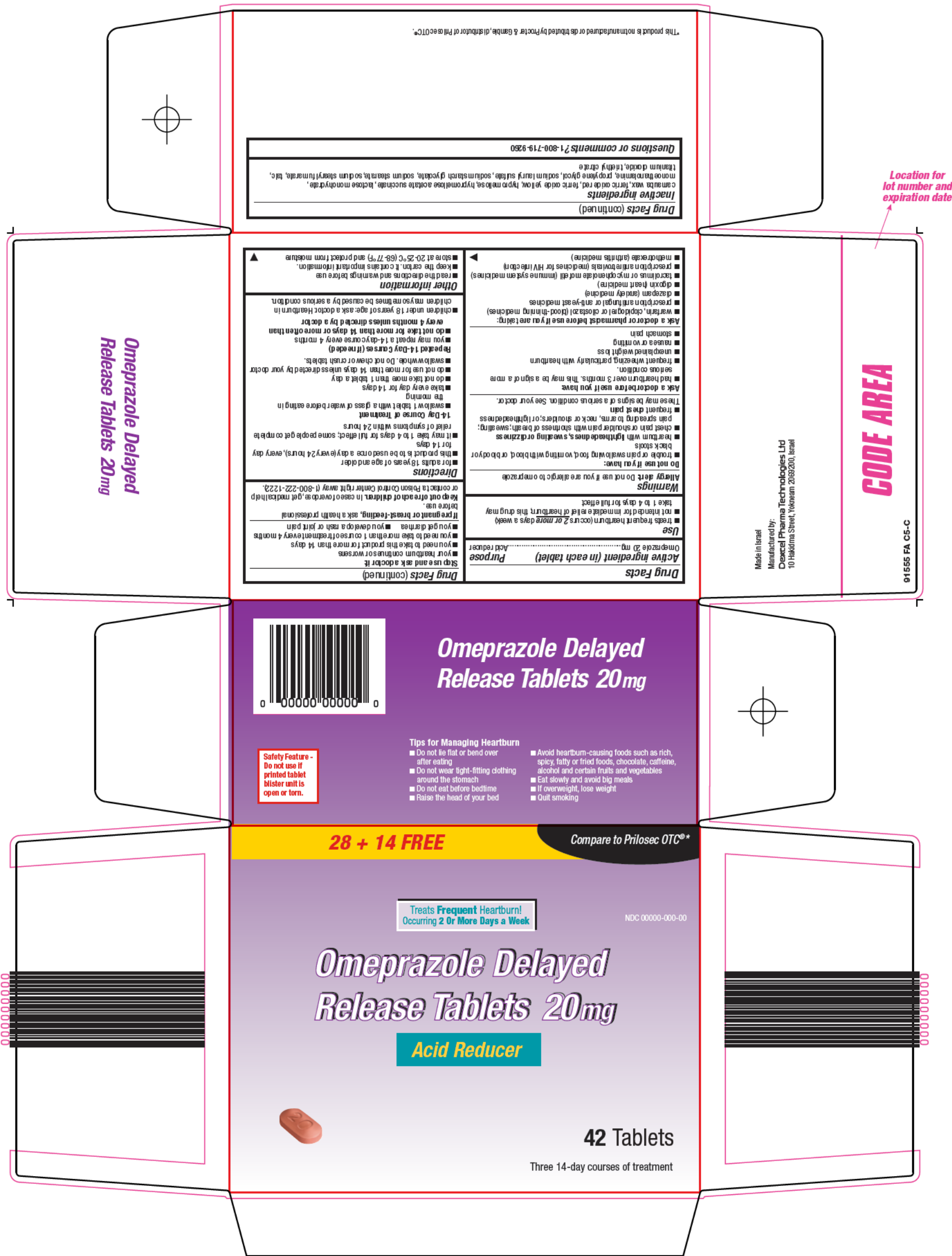
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TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
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HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
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TEXT: 6 pt Helvetica Neue 57 Condensed
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

Omeprazole Delayed Release Tablets, 20 mg
42 Tablets (Bottle Carton)



7-10-17

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



Reference ID: 4179522

7-10-17

STANDARD FORMAT

TYPE SIZES:

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



91000 FA 00-E

Made in Israel
Manufactured by:
Oxcel 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

Compare to Prilosec OTC®*

NDC 00000-000-00

Acid Reducer

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

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)

0000000000

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

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

0000000000

CODE AREA

915D7 FA C5-E

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
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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

Reference ID: 4179522

7-10-17

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

7-10-17

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

0000000000

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

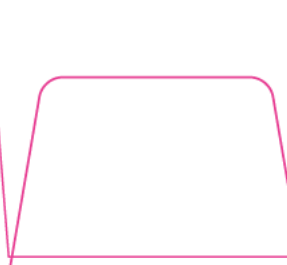
14-Day Course of Treatment
■ swallow 1 tablet with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ swallow whole. Do not chew or crush tablets.

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

0000000000



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

Questions or comments?
1-800-719-9260

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

*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

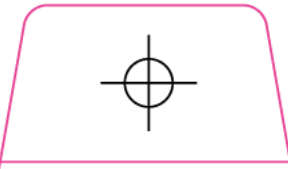
Acid Reducer **42 ~~28~~ Tablets**

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

00000000000000000000

CODE AREA

915D7 FA C5-D



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

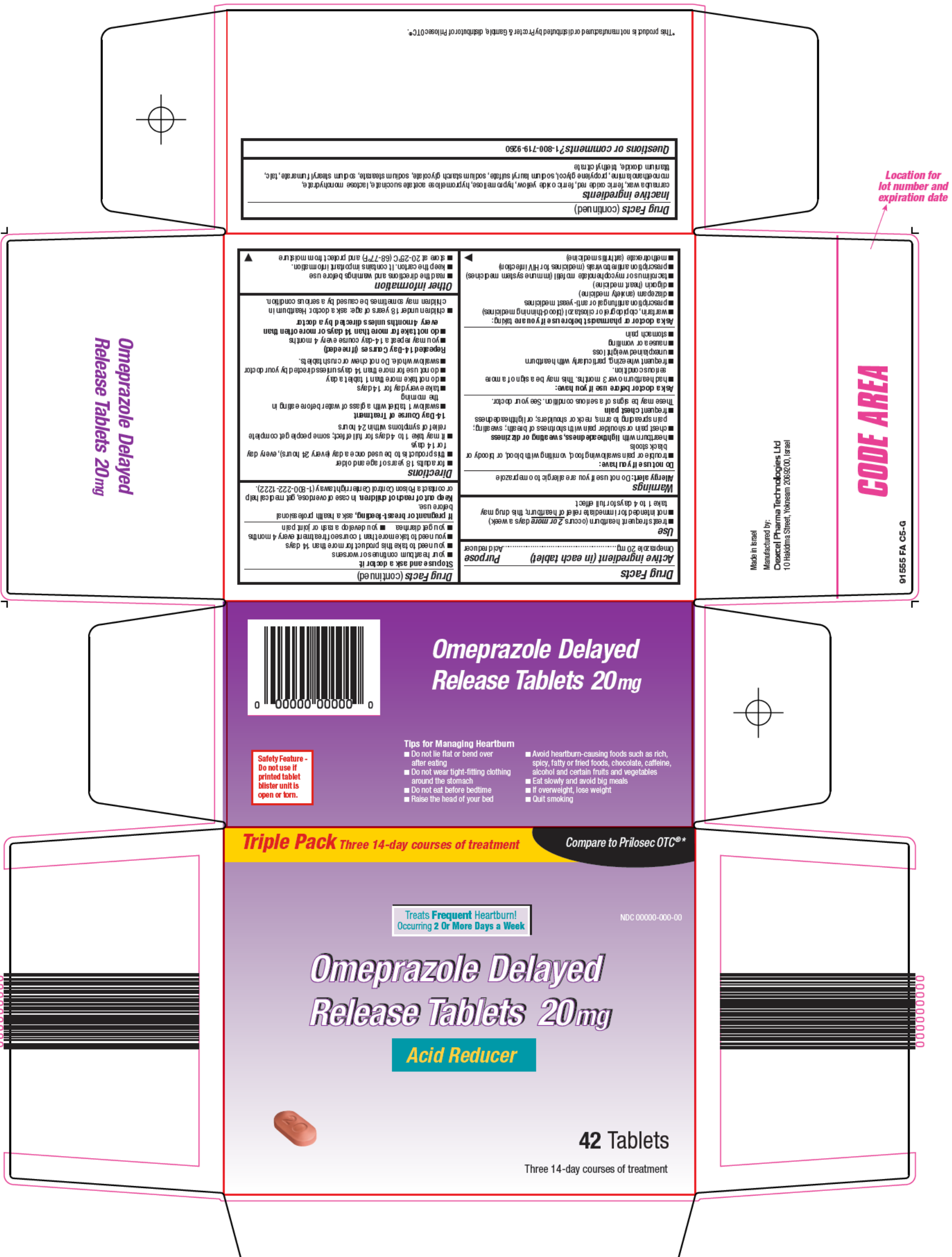
NDC 00000-000-00

Location for
lot number and
expiration date

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**



Reference ID: 4179522

7-10-17

STANDARD FORMAT

TYPE SIZES:

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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)

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



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

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

Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg.....Acid reducer

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - 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 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

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

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

0000000000

Drug Facts

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

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

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

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

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

000000-0000-00

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

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CODE AREA

915D7 FA C5-A

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

Reference ID: 4179522

7-10-17

Made in Israel
Manufactured by:
Dexcel Pharmaceuticals Ltd
10 Haddadim Street, Yokneam 265000, Israel

*This product is not manufactured or distributed by F. Hoffmann–La Roche & Gamble, distributor of Philease OT®.

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

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

CODE AREA

Compare to Prilosec OTC®*

NDC 00000-000-00

Value Pack!

3-14 Tablet Cartons

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment



STANDARD FORMAT

TYPE SIZES:
TITLE: 10 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
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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
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BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HORIZONTAL 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 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

Value Pack!

3-14 Tablet Bottles

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Compare to Prilosec OTC®*

MDC 00000-0000-00

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

0 00000 00000 0

CODE AREA

915D7 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

Reference ID: 4179522

7-10-17

Proposed Draft Labeling

NDA 22-032

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

<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Swallow whole. Do not chew, crush, or suck tablets. One 14-day course of treatment. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.</p> <p>40100 00 X2</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>
<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>Coated with wildberry mint flavor Omeprazole DR Tablets 20mg Acid reducer</p> <p>Push tablet through foil. Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>

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? 1-800-719-9260</p> <p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20°-25°C (68°-77°F) and protect from moisture 	<p>Drug Facts</p> <p>Active Ingredient Purpose (in each tablet)</p> <p>Omeprazole 20 mg..... Acid reducer</p> <p>Use ■ 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>Safety Feature - Do not use if printed seal under cap is broken or missing. This label does not contain full product information. See carton for complete information, Read warnings and directions on carton before use. See full carton for reference.</p> <p>NOT FOR RESALE</p> <p>Treats Frequent Heartburn! Occurring 2 Or More Days a Week</p> <p>Omeprazole Delayed Release Tablets 20mg</p> <p>Acid Reducer</p> <p>SWALLOW - DO NOT CHEW</p> <p>Crated with Wildberry Mint Flavor</p> <p>14 Tablets</p> <p>One 14-day course of treatment</p>	<p>Manufactured by: Oxasent Pharma Technologies Ltd 10 Hekdim Street, Yoknein 208200, Israel Made in Israel</p> <p>CODE AREA</p> <p>* no varnish * no color</p> <p>: 40105 FA F2</p>
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Location for lot number and expiration date

MODIFIED FORMAT

TYPE SIZES:

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 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

4-25-17

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

Tips for Managing Heartburn

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

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

Location for
lot number and
expiration date

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Haddana Street, Yokneam 206800, Israel

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

Questions or comments? 1-800-719-9260

FD-Ciba #2/ndg o carmine aluminum lake, the vort hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, butylsulfate, sodium starch glycolate, sodium stearate, sodium lauryl sulfate, sucrose, talc, titanium dioxide, thacetin, triethyl citrate

Inactive Ingredients

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

Other Information

■ Children under 18 years of age, ask a doctor. Headache 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)
■ Swallow whole. Do not chew, crush, or suck tablets.
■ 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
■ Take every day for 14 days
■ 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 for 14 days
■ This product is to be used once a day (every 24 hours), every day for 14 days
■ For adults 18 years of age and older
■ For children 12 years of age and older
■ For children 12 years of age and older
or contact a Poison Control Center (1-800-222-1222).

Drug Facts (continued)

Active Ingredient (in each tablet)

Omeprazole 20 mg (delayed release tablet)

Purpose

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

■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

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

■ Do not use if you have:

■ Trouble or pain swallowing food, vomiting with blood, or bloody or black stools

■ Heartburn with nighttime sweating, or dizziness

■ Chest pain or shoulder pain with shortness of breath, sweating, or fainting

■ 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.

■ Unexplained weight loss

■ Frequent wheezing, particularly with heartburn

■ 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)

■ Digoxin (heart medicine)

■ Tacrolimus or mycophenolate mofetil (immune system medicines)

■ Prescription anti-hepatitis B virus (medicines for HIV infection)

■ Methotrexate (anti-cancer 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 get diarrhea

■ You develop a rash or joint pain

■ If pregnant or breastfeeding, ask a health professional before use.

CODE AREA

40174 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 000000-000-00

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

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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)



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







Drug Facts (continued)

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

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

Stop use and ask a doctor if:

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

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

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

FDA Approved 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

 **Coated with Wildberry Mint Flavor**

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

 0 00000 00000 0

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

CODE AREA

401D5 FA C3-F





Location for lot number and expiration date

MODIFIED FORMAT

TYPE SIZES:

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TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
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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 PiliSec OTC®.

Drug Facts (continued)

sucinate, 4; glucose monophosphate, 5; modified starch, 6; polyethylene glycol 3350, sodium lauryl sulfate, sodium

Questions or comments? 1-800-719-9260

**Location for
lot number and
expiration date**

CODE AREA

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

40130 FA C3

Omeprazole Delayed Release Tablets 20 mg

Drug Facts

Active ingredient (in each tablet) Omeprazole 20 mg.

Active ingredient (in each tablet)

Warnings

- treats the **current** 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

Do not use if you have

- **black stools**
- **nausea or pain** swallowing food, vomiting with blood, or blood in the stool
- **heartburn with light-headedness, sweating or dizziness**

Ask a doctor before use if you have:

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

nausea or vomiting

■sto mach pain

■ **anxiety** (an'kai-tye) *n* ■

- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)

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®**

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

28 Tablets

Two 14-day courses of treatment

Coated with
Wildberry Mint Flavor



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



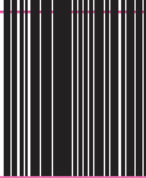
STANDARD FORMAT

TYPE SIZES:

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

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

000000000



Drug Facts (continued)

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus 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? 1-800-719-9260

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

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

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 Tablets

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

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - 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

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

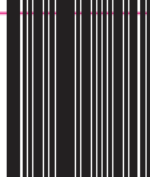
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HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

000000000



Drug Facts (continued)

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus 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? 1-800-719-9260

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

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

Tips for Managing Heartburn

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

FDA Approved

Compare to Prilosec OTC®*

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

28 Tablets

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-F

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

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

**Location for
lot number and
expiration date**

CODE AREA

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

14 FREE

NDC: 00000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

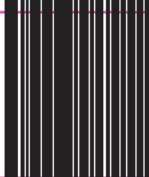
28 Tablets

Two 14-day courses of treatment

TYPE SIZES:
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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)

0000000000



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

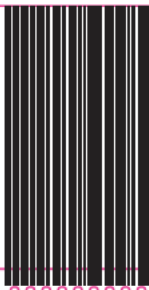
Inactive ingredients benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium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

Questions or comments? 1-800-719-9260

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

Made in Israel

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



0000000000

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

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 Tablets

Two 14-day courses of treatment
 2 BOTTLES INSIDE



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

CODE AREA

401D6 FA C3-B

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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

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**

*This product is not manufactured or distributed by Procter & Gamble, distributor of OFF! insecticide.

**Location for
lot number and
expiration date**

CODE AREA

40130 FA C5-E

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

Omeprazole Delayed Release Tablets 20mg

Drug Facts (continued)

Inactive ingredients

benzyl alcohol, camphor, carmellose wax, FD&C blue #2, hydrocortisone succinate, lactose monohydrate, methylcellulose, modified starch, monodistilled glycolic acid, sodium stearate, sodium steryl fumarate, sucrose

Questions or comments? 1-800-771-9128

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● Stop use and ask a doctor if: ■ you are having continuous or worsening symptoms ■ you need to take this product for more than 14 days ■ your condition does not improve after 1 course of treatment every 4 months ■ you get dizziness ● you develop a rash or joint pain ■ If pregnant or breastfeeding, ask a health professional before use. <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> <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), everyday ■ 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 after 14-Day Course (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: caused by a serious condition, consult your doctor or pharmacist for advice. <p>Other information</p> <ul style="list-style-type: none"> ■ read the directions on warm beverages use ■ keep the carton, it contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture 	<p>Purpose</p> <p>Acetaminophen (in each tablet) Ibuprofen 20 mg</p> <p>Drug Facts</p> <p>Active ingredient (in each tablet) Acetaminophen 20 mg Ibuprofen 20 mg</p> <p>Use</p> <p>Take as frequent headache (occurs 2 or more days a week) or not intended for immediate relief of headache. (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 acetaminophen</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 high badness, swelling or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating or light spreading to arms, neck or shoulders, or high blood pressure ■ request chest pain <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> ■ had headache over 3 months. This may be a sign of a more serious condition. ■ trouble wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> ■ warfarin, clopidogrel or clozapine (blood-thinning medicines) ■ prescription oral fungal or anti-fungal medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription oral steroids (medicines for HIV infection) ■ methotrexate (arthritis medicine)
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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

Bonus! 14 Free

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

28 ~~14~~ Tablets

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



Coated with
Wildberry Mint Flavor

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) **8 pt Helvetica Neue 57 Condensed**
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 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

Reference ID: 4179522

7-11-17

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

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Drug Facts (continued)

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus 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? 1-800-719-9260

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! 14 Free

Compare to Prilosec OTC®*

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

28 14 Tablets

Coated with
Wildberry Mint Flavor

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



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

CODE AREA

401D6 FA C3-E

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - 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

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
(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

*This product is not manufactured or distributed by Procter & Gamble, its tributary or affiliated OTCC.

Questions or comments? 1-800-719-9260

inactive ingredients

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Drug facts (continued)

Other information

- Other information**
- The product is to be used once a day (every 24 hours), every day for adults 18 years of age and older
 - I 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 1 tablet a day
 - do not take 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. He or she will inform you if sometimes be caused by a serious condition.
- store at 20-25°C (68-77°F) and protect from moisture
- Keep the carton, if available, until after use.
- Read the directions and warnings before use.

Directions

Warning signs (continued)

- Stop seeing and ask a doctor if:
 - you're having continuous or worsens
 - you need to take the product for more than 14 days
 - you need to take more than 1 course of treatment every 4 months
 - you get dizziness
 - you get pain or breast/tender swelling
- If you develop a rash or joint pain
- If pregnant or breastfeeding, ask a health professional for advice
- Keep up and read instructions in case of a dose, get medical help or contact a Poison Control Center (1-800-222-2222).

Drug Facts (continued)

Purpose

g.....Acid reducer

(in each table)

Drug Facts

as

- 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

ore use if you have:

- These may be signs of a serious condition. See your doctor.
- Ask a doctor before use if you have:**
- had health run over 3 months. This may be a sign of a more serious condition.
 - frequent wheezing, particularly with heartbeat
 - unexplained weight loss
 - nausea or vomiting
 - stomach pain

Pharmacist before use if you are taking:

- [illegible]

**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

SWALLOW - DO NOT CHEW



Coated with
Wildberry Mint Flavor

28 ~~14~~ Tablets

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

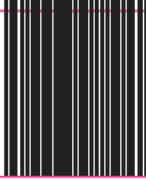
STANDARD FORMAT

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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 (Wildberry Mint)
28 Tablets (Bottle Carton)

0000000000



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? 1-800-719-9260

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

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

28 Tablets

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)
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

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**

Location for lot number and expiration date

CODE AREA

40155 FA C3

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

Drug Facts (continued)

Inactive ingredients
FD&C blue #2, indigo carmine, aluminum lake, flavor, hypromellose, acetate, sucralose, lactose monohydrate, methylcellulose, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triethyl citrate.

Questions or comments? 1-800-719-9260

This product is not manufactured or distributed by P. Richter & GmbH, distributor of Prilosec OTC.

Drug Facts

Active ingredient (in each tablet)
Omeprazole 20 mg

Purpose
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
■ 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, 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 weight loss
■ Unexplained weight loss
■ Nausea or vomiting
■ Stomach pain

Ask a doctor or pharmacist before use if you are taking:
■ Warfarin, clopidogrel or clostazepam (blood-thinning medicines)
■ Digoxin (heart medicine)
■ Disopram (anxiety medicine)
■ Tacrolimus or mycophenolate mofetil (immune system medicines)
■ Pseudoephedrine (decongestant)
■ Methotrexate (cancer medicine)

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

Directions
■ For adults 18 years of age and older:
■ This product is to be used once a day (every 24 hours), every day for 14 days.
■ It may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.
■ 14-Day Course of Treatment
■ Swallow 1 tablet with a glass of water before eating in the morning.
■ Take every day for 14 days.
■ Do not take more than 1 tablet a day.
■ Do not use for more than 14 days unless directed by your doctor.
■ Swallow whole. Do not chew, crush, or suck tablets.
■ 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 for more than 14 days.
■ You need to take this product for more than 14 days.
■ You get diarrhea.
■ If pregnant or breast-feeding, ask a health professional before use.
■ Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Drug Facts (continued)

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.

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

42 Tablets

Coated with **Wildberry Mint Flavor**

Three 14-day courses of treatment

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 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)

0000000000

Drug Facts

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

Purpose

Use

Warnings

Drug Facts (continued)

Stop use and ask a doctor if:

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

Directions

14-Day Course of Treatment

Repeated 14-Day Courses (if needed)

Other information

Drug Facts (continued)

Inactive ingredients

Questions or comments?

Made in Israel

Manufactured by:

10 Hakidma Street, Yokneam 2069200, Israel

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

Tips for Managing Heartburn

Compare to Prilosec OTC®*

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

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Coated with
Wildberry Mint Flavor

CODE AREA

40174 FA C3

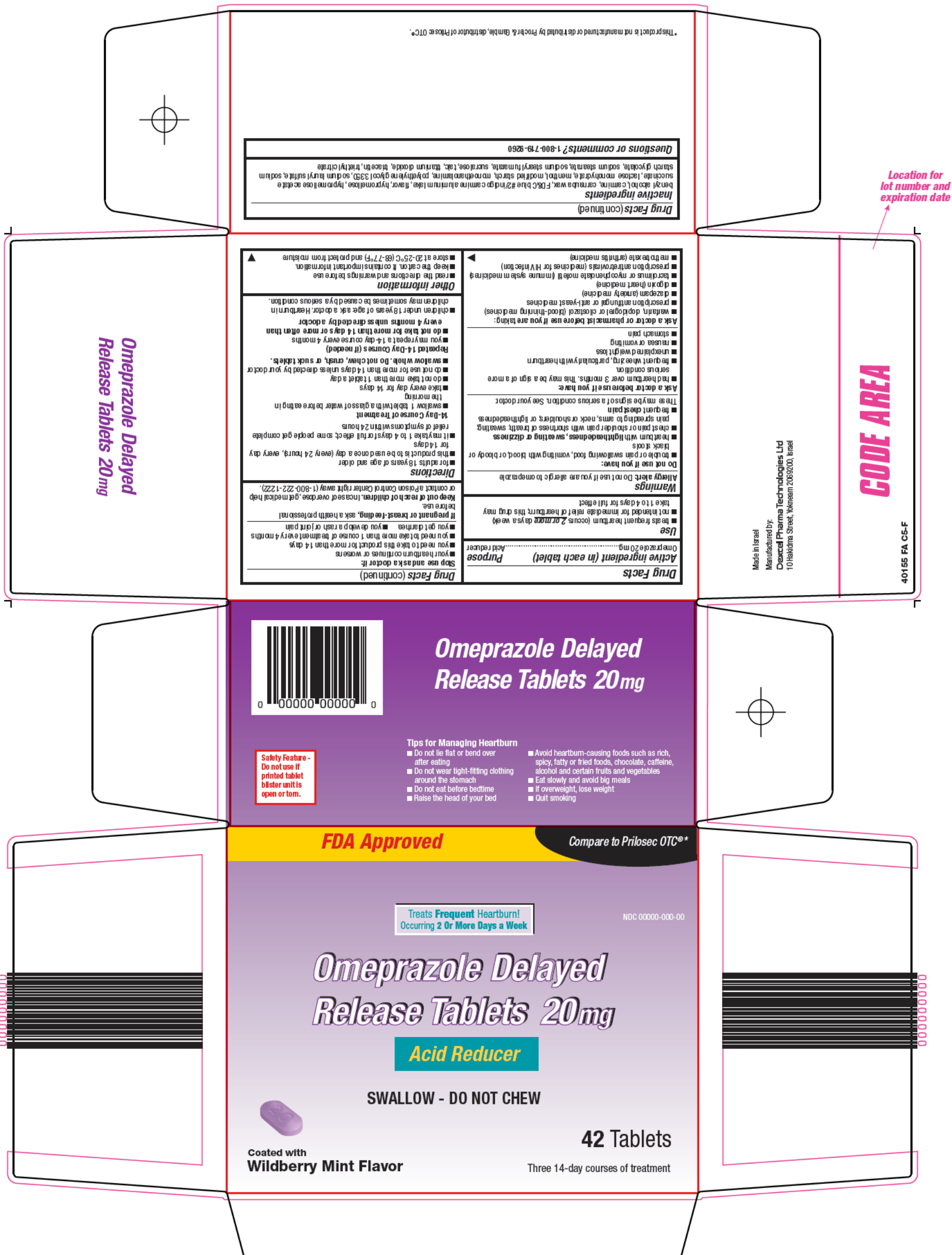
Safety Feature -
Do not use if printed seal under cap is broken or missing

Location for lot number and expiration date

STANDARD FORMAT

TYPE SIZES:
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TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
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SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 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



**Location for
lot number and
expiration date**

CODE AREA

40100 FA 03-F

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

Drug Facts	Active ingredient (in each tablet) Omeprazole 20 mg.....acid reducer
Use Use as directed for heartburn (occurs 2 or more days a week) or to help prevent or immediately relieve 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 • heartburn with light-headedness, sweating or dizziness • chest pain or shoulder pain with shortness of breath, sweating, or pain spreading to arms, neck, or shoulders, or lightheadedness • any heart chest pain The signs may be of a serious condition. See your doctor.	Ask a doctor before use if you have • heartburn over 3 months. This may be a sign of a more serious condition. • any heart, wheezing, or shortness of breath • unexplained weight loss • nausea or vomiting • stomach pain Ask a doctor or pharmacist before use if you are taking: • warfarin (doploide) or clostazol (blood-thinning medicines) • prescription anti-ulcer or anti-acid medicines • dexam (acetylsalicylic acid) • aspirin (heart medicine) • other medicines or over-the-counter medicines (ask your pharmacist for a list of medicines)

Drug Facts (continued)

Use and ask a doctor if:

- your heartburn or reflux 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

Read the directions and warnings before use.

Keep out of reach of children. In case of overdose, get medical help or contact 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)
- (1) measure 1 to 4 days if you feel some people get complete relief of symptoms within 24 hours
- (2) swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not use for more than 14 days unless directed by your doctor or pharmacist
- do not use for more than 14 days or more often than directed
- you may need a 14-day course every 4 months
- you may need a 14-day course every 4 months

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 cap on it to keep it moist and to prevent from moisture
- store at 25°C (68°F to 77°F) and protect from moisture

Omeprazole Delayed Release Tablets 20 mg

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.

FDA Approved

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

Three 14-day courses of treatment

Coated with
Wildberry Mint Flavor

STANDARD FORMAT

TYPE SIZES:

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

7-11-17

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.....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
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 Hakdima 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

Coated with
Wildberry Mint Flavor

Omeprazole Delayed Release Tablets 20mg

Acid Reducer
SWALLOW - DO NOT CHEW

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

CODE AREA

40174 FA C3-F

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

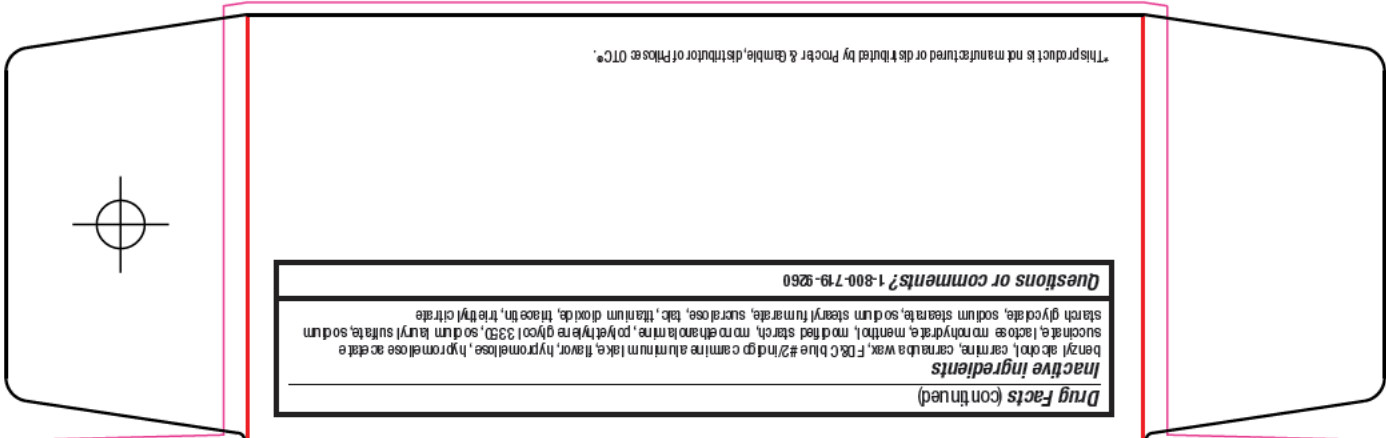
Location for lot number and expiration date

Reference ID: 4179522

STANDARD FORMAT
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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

7-11-17

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



**Location for
lot number and
expiration date**

CODE AREA

401001A 00-B

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

Omeprazole Delayed Release Tablets 20 mg

Drug Facts	Active ingredient (in each tablet) Omeprazole 20 mg.....acid reducer
Use ● Beats 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 or pain swelling 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 ● The most chest pain!	
Directions ● For adults 18 years of age and older ● This product is to be used once a day (every 24 hours, every day, 14 days) ● I will take 1 to 4 days or full effect; some people get complete relief of symptoms within 24 hours ● 14-Day Course of Treatment ● Swallow 1 tablet with 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 or pharmacist ● Swallow whole. Do not chew, crush, or suck tablets. ● Repeated 14-day Courses (if needed) ● Repeat 1 tablet every 4 months ● Every 4 months unless directed by a doctor ● Children under 13 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 cap on. It could lose important information. ● Store at 20-25°C (68-77°F) and protect from moisture.	
Drug Facts (continued) Stop use and ask a doctor if: ● Your heartburn continues or worsens ● You need to take this product for more than 14 days ● You need to take more than 1 course of the treatment every 4 months ● You get diarrhea ● You develop a rash or joint pain If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).	

Omeprazole Delayed Release Tablets 20mg

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- 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.

Compare to Prilosec OTC®*

NDC 00000-000-00

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

14 FREE

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment



Coated with
Wildberry Mint Flavor

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 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

7-11-17

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

<h2>Drug Facts</h2> <table border="1"> <tr> <th>Active ingredient (in each tablet)</th> <th>Purpose</th> </tr> <tr> <td>Omeprazole 20 mg.....</td> <td>Acid reducer</td> </tr> </table>		Active ingredient (in each tablet)	Purpose	Omeprazole 20 mg.....	Acid reducer
Active ingredient (in each tablet)	Purpose				
Omeprazole 20 mg.....	Acid reducer				
<p>Use</p> <ul style="list-style-type: none"> ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect 					
<p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</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>					
<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 					
<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) 					
<h2>Drug Facts (continued)</h2> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>					
<p>Directions</p> <ul style="list-style-type: none"> ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. 					
<p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture 					

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

40174 FA C3-B

Reference ID: 4179522

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

0000000000

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

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

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Coated with Wildberry Mint Flavor

000000000000

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

STANDARD FORMAT

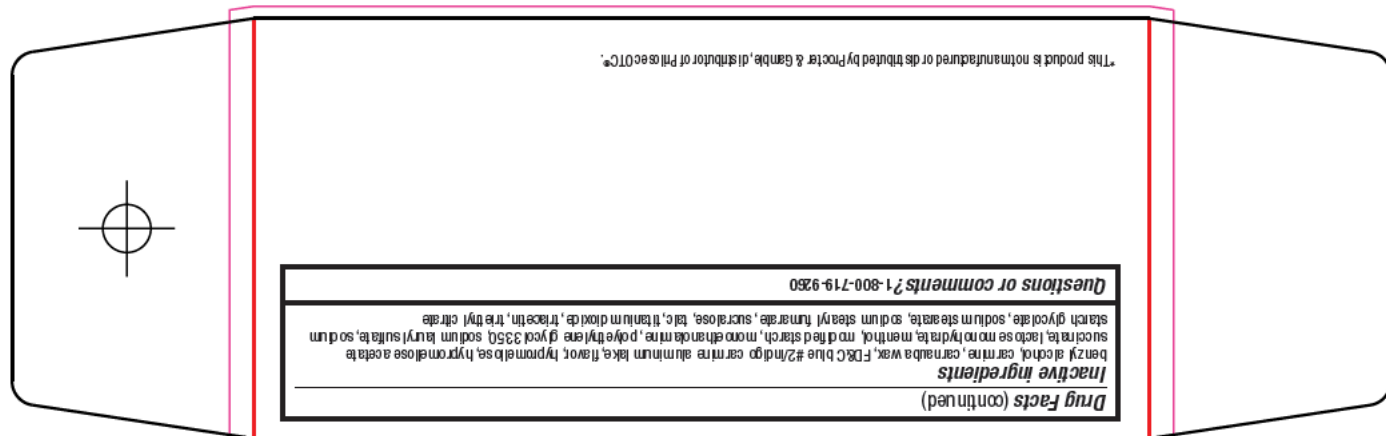
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TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Reference ID: 4179522

7-11-17

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



**Location for
lot number and
expiration date**

CODE AREA

40155 FA C5-E

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

Omeprazole Delayed Release Tablets 20 mg

<p>Drug Facts</p> <p>Use</p> <p>• Takes 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 meclizine</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> • trouble or pain swallowing food, no reflux with blood, or blood or black stools • heartburn with nighttime distress, swelling or dizziness • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck or shoulders, or lightheadedness <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 weight gain, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> • warfarin, ciprofloxacin or clozapine (blood-thinning medicines) • prescription or over-the-counter acid-reducing medicines • diazepam (anxiety medicine) • digoxin (heart medicine) • tacrolimus or mycophenolate mofetil (immune system medicines) • prescription or over-the-counter medicines for HIV (the chits) • methotrexate (anti-cancer medicine) <p>Unpackaged 20 mg _____</p> <p>Purpose</p> <p>• To reduce _____</p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • your heartburn continues or worsens • you need to take this product for more than 14 days • you need to take more than 1 course of treatment every 4 months • you get dizziness • you get diarrhea <p>If pregnant or breast-feeding, ask a health professional before use.</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> <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 14 hours <p>14 Day Course of Treatment</p> <ul style="list-style-type: none"> • Swallow 1 tablet with a glass of water before eating in the morning • Take every day for 14 days • Do not take more than 1 tablet a day • Do not use for more than 14 days unless directed by your doctor • Swallow whole. Do not chew, crush, or suck tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> • You may repeat a 14-day course every 4 months • Do not take for more than 14 days or more often than every 4 months unless directed by a doctor • Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none"> • Read the directions and warnings before use • Keep the carton. It contains important information. • Store at 20-25°C (68-77°F) and protect from moisture 	<p>▶</p>
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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

Bonus! 14 Free

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



Coated with
Wildberry Mint Flavor

42 ~~28~~ Tablets

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

STANDARD FORMAT

TYPE SIZES:

TYPE SIZES:
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HAIRLINES: 0.5 pt

7-11-17

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



STANDARD FORMAT

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TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

<p>Drug Facts (continued)</p> <p>Inactive Ingredients</p> <p>benzyl alcohol, camphor, FD&C blue #2, indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, maltodextrin, modified starch, monothenoamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearoyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate</p>	<p>Questions or comments? 1-800-719-9260</p>
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* This product is not manufactured or distributed by Procter & Gamble, distributed off license, OTC.

CODE AREA

40155 FA C3-D

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Ha-kidma Street, Yokneam 2069200, Israel

Omeprazole Delayed Release Tablets 20 mg

[illegible]

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

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 ~~28~~ Tablets

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

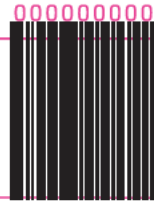
Coated with
Wildberry Mint Flavor

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 (Bottle Carton)**



<h2>Drug Facts</h2> <table border="0"> <tr> <td>Active ingredient (in each tablet)</td> <td>Purpose</td> </tr> <tr> <td>Omeprazole 20 mg</td> <td>Acid reducer</td> </tr> </table>		Active ingredient (in each tablet)	Purpose	Omeprazole 20 mg	Acid reducer
Active ingredient (in each tablet)	Purpose				
Omeprazole 20 mg	Acid reducer				
<p>Use</p> <ul style="list-style-type: none"> ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect 					
<p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</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> <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 <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) 					
<h2>Drug Facts (continued)</h2> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions</p> <ul style="list-style-type: none"> ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew, crush, or suck tablets. <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture 					

Drug Facts (continued)

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

Questions or comments?
1-800-719-9260

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

*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 00000-000-00

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

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

**CODE AREA**

40174 FA C3-D

STANDARD FORMAT

TYPE SIZES:

TYPE SIZES:
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TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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

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

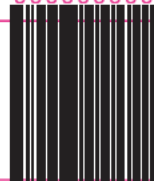


7-11-17



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®.

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

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

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

Coated with
Wildberry Mint Flavor



CODE AREA

40174 FA C3-A

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

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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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:
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

Value Pack!
3-14 Tablet Bottles

Compare to Prilosec OTC®*

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

CODE AREA

40174 FA C3-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

Reference ID: 4179522

7-11-17

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



91574 FA CP4

14 Tablets

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

**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



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

Reference ID: 4179522

8-10-17

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

pay on coupon

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

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

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 880636,
El Paso, TX 88588-0636

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



8-10-17

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



91530 FA CP4

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 88588-0036

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



0 00000 00000 0

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

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.



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

Reference ID: 4179522

8-10-17

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



91555 FA CP4

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

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
42 Count**

Proposed Draft Labeling

NDA 22-032

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

FRONT PANEL

Peel Off
Coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 0000-000-00

Compare to Prilosec OTC®*

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

**Omeprazole Delayed
Release Tablets 20mg**



915D7 FA CP4

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

SAVE \$X^{XX}

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

**COUPON NOT SUBJECT
TO DOUBLING**

Customer pays any sales tax.

CONSUMER: Only one coupon is redeemable
per purchase. RETAILER: This coupon will
be 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 880096,
El Paso, TX 88588-0096



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

Reference ID: 4179522

8-10-17

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 88688-0036

COUPON NOT SUBJECT
TO DOUBLING
Customer pays any sales tax.



Omeprazole Delayed Release Tablets 20 mg 14 Count

Reference ID: 4179522

8-10-17

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

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

SWALLOW - DO NOT CHEW



Coated with
**Wildberry Mint
Flavor**

14 Tablets

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.



8-10-17

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 88588-0036

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



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

Reference ID: 4179522

8-10-17

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

: 40106 FA CP3

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

**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:

NCH, PO Box 880036,
El Paso, TX 88588-0036



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

Reference ID: 4179522

8-10-17

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 \$XXX

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 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
42 Count**

Reference ID: 4179522

8-10-17

Proposed Draft Labeling

NDA 22-032

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

FRONT PANEL

part of
coupon

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

Three 14-day courses of treatment
3 BOTTLES INSIDE



Coated with
Wildberry Mint Flavor

40107 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

**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:
NCH, PO Box 880036,
El Paso, TX 88588-0036



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

Reference ID: 4179522

8-10-17