

**Proposed Draft Labeling
NDA 22-032**

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

000000000

Made in Israel
Manufactured by:
Dexel Pharma
Technologies Ltd.,
10 Hakdima Street,
Yokneam, 20692, Israel

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

NDC 0000-000-00

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

DIE CUT WINDOW

Treat My Heartburn.com

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

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

0000000000

LOT NO. CODE AREA
EXP.
: 91505 FA C9

Drug Facts (continued)

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

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

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

Other Information

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

Inactive Ingredients

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

Questions or comments?
1-800-719-9260

Tips for Managing Heartburn

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

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clobazam (blood-thinning medicines)

000000000

MODIFIED FORMAT

TYPE SIZES:

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

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

Tips for Managing Heartburn

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

Manufactured by:
Cencel Pharma Technologies Ltd.
 10 Haddina Street, Yokneam, 20692, Israel

Made in Israel

<p>Questions or comments? 1-800-719-9260</p> <p>Inactive Ingredients camate wax, ferric oxide red, ferrous sulfate, talc, titanium dioxide, triethyl citrate</p> <p>Other Information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) and protect from moisture ■ keep the carton in a cool, dry place ■ read the directions and warnings before use <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 adults 18 years of age and older ■ 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 ■ Report 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 under 18 years of age is caused by a serious condition. <p>Drug Facts (continued)</p>	<p>Warnings</p> <ul style="list-style-type: none"> ■ Allergy alert: Do not use if you are allergic to omeprazole ■ Do not use if you have or had black stools, vomiting with blood, or blood or pain swallowing food, vomiting ■ Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a serious condition. ■ chest pain or shoulder pain with shortness of breath, sweating, fainting, or dizziness ■ frequent chest pain ■ pain spreading to or from neck, or shoulders, or high back ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain ■ Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel, or clozapine (blood thinning medicines) ■ prescription anti-ulcer or anti-heartburn medicines ■ dexamethasone (steroid) ■ diazepam (heart medicine) ■ tacrolimus or cyclosporine (immunosuppressant medicines) ■ prescription anti-ulcer or anti-heartburn medicines ■ metformin (diabetes medicine) ■ Ask a doctor before use if you are taking ■ any of the following medicines for HIV infection ■ metformin (diabetes medicine) ■ Stop use and ask a doctor if ■ you have heartburn, continue 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 <p>Use</p> <ul style="list-style-type: none"> ■ 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 <p>Purpose</p> <p>Acid reducer</p> <p>Omeprazole 20 mg (each tablet)</p>
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CODE AREA

: 91574 FA CBP3-F



Omeprazole Delayed Release Tablets 20 mg

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

FDA Approved NDC 00000-000-00



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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



14 Tablets

One 14-day course of treatment

MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique

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

HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.3 and 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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

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 Manufactured by:
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 Technologies Ltd.,
 10 Hakidma Street,
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FDA Approved

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Treats Frequent Heartburn!
 Occurring 2 Or More Days a Week

TreatMyHeartburn.com

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Acid Reducer

14 Tablets

One 14-day course of treatment
 1 BOTTLE INSIDE

0000000000

LOT NO. CODE AREA

EXP.
 : 915D5 FA CBP3-F

Drug Facts (continued)

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

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

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

Other Information

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

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

Questions or comments?
 1-800-719-9260

Tips for Managing Heartburn

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

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)

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MODIFIED FORMAT

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

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

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

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

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

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

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

Questions or comments?
 1-800-719-9260

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

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

NDC 0000-000-00

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

DIE CUT WINDOW **DIE CUT WINDOW**

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

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

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

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

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

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

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

LOT NO.
 EXP.
 : 915D6 FA C9

CODE AREA

STANDARD FORMAT

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

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

Tips for Managing Heartburn

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

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

Drug Facts (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

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

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- 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

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- do not take more than 1 tablet a day
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Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

Other information

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

Inactive ingredients

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

Questions or comments?
1-800-719-9260

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

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FDA Approved

DIE CUT WINDOW **DIE CUT WINDOW**

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

00-0000-0000

TreatMyHeartburn.com

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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



LOT NO.
EXP.
: 91566 FA CBP3-F

CODE AREA

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

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

(continued) 8 pt Helvetica Neue 57 Condensed

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

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



Drug Facts (continued)

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- 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)
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Drug Facts (continued)

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Tips for Managing Heartburn

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- Do not eat before bedtime
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- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

NDC 0000-000-00

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

14 FREE

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

TreatMyHeartburn.com

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

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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28 Tablets

Drug Facts (continued)
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Drug Facts (continued)

Use
treats frequent heartburn (occurs 2 or more days a week)
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Warnings
Allergy alert: Do not use if you are allergic to omeprazole
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Ask a doctor before use if you have:
had heartburn over 3 months. This may be a sign of a more serious condition.
heartburn with nighttime awakenings, sweating or dizziness
chest pain or shoulder pain with shortness of breath, sweating, or fainting, or dizziness, particularly with heartburn
request chest pain
repeat chest pain
nausea or vomiting
stomach pain
Ask a doctor or pharmacist before use if you are taking:
warfarin, clopidogrel, or clostridium (blood-thinning medicines)
prescription antifungal or anti-yeast medicines
diazepam (anxiety medicine)
digoxin (heart medicine)
tacrolimus or mycophenolate mofetil (immune system medicines)
prescription antiretrovirals (medicines for HIV infection)
methotrexate (arthritis medicine)

Active ingredient (in each tablet)
Omeprazole 20 mg, hydrochloride

Purpose
Acid reducer

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

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

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

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

Made in Israel

CODE AREA

: 91530 FA CBP3-E

Omeprazole Delayed
Release Tablets 20mg

Omeprazole Delayed Release Tablets 20mg

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

Tips for Managing Heartburn

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

Bonus! 14 Free NDC 00000-000-00

Treat My Heartburn.com

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

28 ~~14~~ Tablets
Two ~~One~~ 14-day courses of treatment

STANDARD FORMAT

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

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

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

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

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

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

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

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

Questions or comments?
 1-800-719-9260

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

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

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

Bonus! 14 Free

DIE CUT WINDOW **DIE CUT WINDOW**

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

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

28 14 Tablets

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

00-000-0000-0000

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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.
 ■ heartburn with **lightheadedness, sweating or dizziness**
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ frequent chest pain
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting ■ stomach pain ▶



LOT NO.
 EXP.
 : 915D6 FA CBP3-E

CODE AREA

STANDARD FORMAT

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

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

Drug Facts (continued)
Inactive ingredients
canalra a wa, ferric oxide red, hypromellose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260

Drug Facts
Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer
Purpose
Use
■ treats the frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect
Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or body or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
■ heartburn over 3 months. This may be a sign of a more serious condition.
■ heartburn with nighttime aches, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulder, or lightheadedness
■ frequent chest pain
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain
Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel, or clostazid (blood-thinning medicines)
■ diazepam (anxiety medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antifungal or anti-yeast medicines
■ dicyclanil (heart medicine)
■ telicaps or mycophenolate mofetil (immune system medicines)
■ prescription antifungal or anti-yeast medicines
■ dicyclanil (heart medicine)
■ telicaps or mycophenolate mofetil (immune system medicines)
■ prescription antifungal or anti-yeast medicines
■ dicyclanil (heart medicine)
■ methotrexate (arthritis medicine)
Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F) and protect from moisture
▲

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

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

Omeprazole Delayed Release Tablets 20 mg

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

CODE AREA

: 91530 FA CBP3-D



Omeprazole Delayed Release Tablets 20mg

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

Tips for Managing Heartburn

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

Bonus Pack! 14 Free NDC 00000-000-00



Treats Frequent Heartburn! Occurring 2 Or More Days a Week

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 ~~14~~ Tablets

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

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

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



Tips for Managing Heartburn

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

Drug Facts (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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Drug Facts (continued)

Other information

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

Inactive ingredients

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

Questions or comments?

1-800-719-9260

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

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

Bonus Pack! 14 Free

DIE CUT WINDOW

DIE CUT WINDOW

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week



Omeprazole Delayed Release Tablets 20mg

Acid Reducer



28 14 Tablets

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

Drug Facts

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

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

STANDARD FORMAT

TYPE SIZES:

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

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

000000000



Drug Facts

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

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

Warnings

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking

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

Drug Facts (continued)

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

Other information

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

Drug Facts (continued)

Inactive ingredients

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

Questions or comments?

1-800-719-9260

Made in Israel

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

NDC 0000-000-00

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

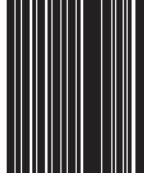
42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE



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

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000000000



LOT NO.

EXP.

: 935D7 FA C9

CODE AREA

STANDARD FORMAT

TYPE SIZES:

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

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



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

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ heartburn with lightheadedness, sweating or dizziness
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain
Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus 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
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

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

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

Questions or comments?
1-800-719-9260

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

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

FDA Approved

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

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

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

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

TreatMyHeartburn.com

Barcode: 0 000000 000000 0

LOT NO.
EXP.
: 915D7 FA CBP3-F

CODE AREA

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

NDC 0000-0000-00

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

**Omeprazole Delayed
Release Tablets 20mg**

Drug Facts (continued)
Active ingredient (in each tablet).....Omeprazole 20 mg.....Acid reducer
Use
■ Treats frequent heartburn (occurs 2 or more days a week)
■ Not intended for immediate relief of heartburn; (treatment may take 1 to 4 days for full effect)
Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
■ Had heartburn over 3 months. This may be a sign of a more serious condition.
■ Heartburn with lightheadedness, sweating or dizziness
■ Chest pain or shoulder pain with shortness of breath, sweating, or lightheadedness.
■ Treat chest pain
■ Treat weight loss, particularly with heartburn
■ Unexplained weight loss
■ Nausea or vomiting
■ Stomach pain
Ask a doctor or pharmacist before use if you are taking
■ Warfarin, clopidogrel or other blood-thinning medicines
■ Prescription antifungal or anti-yeast medicines
■ Digoxin (heart medicine)
■ Azapem (anxiety medicine)
■ Tacrolimus or mycophenolate mofetil (immune system medicines)
■ Prescription antiretrovirals (medicines for HIV infection)
■ Methotrexate (arthritis medicine)

Drug Facts (continued)
Other information
■ Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
■ Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.
■ You may repeat a 14-day course every 4 months.
■ Repeat 14-Day Courses if needed.
■ Do not take more than 14 days unless directed by your doctor.
■ Do not take more than 1 tablet a day.
■ Take every day for 14 days.
■ The morning
■ Swallow 1 tablet with a glass of water before eating in 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.
■ For adults 18 years of age and older (every 24 hours), every day.
■ This product is to be used once a day.
■ 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
■ 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
■ If pregnant or breast-feeding, ask a health professional before use.
■ Take 1 to 4 days for full effect.
Warnings
Do not use if you are allergic to omeprazole
■ Treats frequent heartburn (occurs 2 or more days a week)
■ Not intended for immediate relief of heartburn; (treatment may take 1 to 4 days for full effect)
Use
■ Treats frequent heartburn (occurs 2 or more days a week)
■ Not intended for immediate relief of heartburn; (treatment may take 1 to 4 days for full effect)
Warnings
Do not use if you are allergic to omeprazole
■ Heartburn with lightheadedness, sweating or dizziness
■ Chest pain or shoulder pain with shortness of breath, sweating, or lightheadedness.
■ Treat chest pain
■ Treat weight loss, particularly with heartburn
■ Unexplained weight loss
■ Nausea or vomiting
■ Stomach pain
Ask a doctor or pharmacist before use if you are taking
■ Warfarin, clopidogrel or other blood-thinning medicines
■ Prescription antifungal or anti-yeast medicines
■ Digoxin (heart medicine)
■ Azapem (anxiety medicine)
■ Tacrolimus or mycophenolate mofetil (immune system medicines)
■ Prescription antiretrovirals (medicines for HIV infection)
■ Methotrexate (arthritis medicine)

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

CODE AREA

91555 FA CBP3-B



**Omeprazole Delayed
Release Tablets 20mg**

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

Tips for Managing Heartburn

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

14 FREE



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



42 Tablets

Three 14-day courses of treatment

STANDARD FORMAT

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

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



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

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

Questions or comments?
1-800-719-9260

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

NDC 0000-000-00

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

14 FREE

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

TreatMyHeartburn.com

CODE AREA

LOT NO.
EXP.
: 915D7 FA CBP3-B

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

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

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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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

**Omeprazole Delayed
Release Tablets 20mg**

CODE AREA

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

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

Purpose
Stop use and ask a doctor if your heartburn continues or worsens or you need to take this product for more than 14 days

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

Warnings
Allergy alert: Do not use if you are allergic to omeprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
heartburn with nighttime aches, sweating or dizziness chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness frequent chest pain frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain

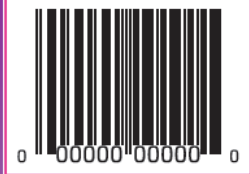
Ask a doctor or pharmacist before use if you are taking
warfarin, clopidogrel, or clostazepate (blood-thinning medicines) proton pump inhibitors or anti-yeast medicines diazepam (anxiety medicine) dextromethorphan (cough medicine) or H₂ blocker (heartburn medicine) or other drugs that may interact with omeprazole

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

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

Manufactured by:
Dexal Pharma Technologies Ltd.
10 Hakdima Street, Yokneam, 20692, Israel
Made in Israel

91555 FA CBP3-E



**Omeprazole Delayed
Release Tablets 20mg**

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

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

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

Bonus! 14 Free

NDC 00000-000-00



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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer

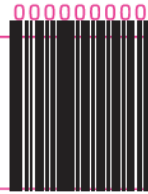


42 ~~28~~ Tablets

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

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
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TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 and 6.7 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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



Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg		Purpose Acid reducer	
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect		Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clobazepam (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)		Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.	
Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture			



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

Questions or comments?
1-800-719-9260

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

Tips for Managing Heartburn

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

Bonus! 14 Free

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW



Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 ~~28~~ Tablets

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



LOT NO.

EXP.

: 915D7 FA CBP3-E

CODE AREA

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

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
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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
42 Tablets (Bottle Carton)

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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or 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 If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. Other information ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

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

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

Tips for Managing Heartburn

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

Bonus Pack! 14 Free

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 ~~28~~ Tablets

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

0 00000 00000 0

LOT NO.

EXP.

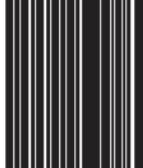
: 915D7 FA CBP3-D

CODE AREA

NDC 0000-000-00

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

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STANDARD FORMAT

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

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

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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or clostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)	
Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. Other information ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

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

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

Tips for Managing Heartburn

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

Bonus Pack! 14 Free **Treats Frequent Heartburn!**
Occurring 2 Or More Days a Week

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

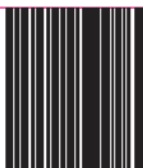
42 ~~28~~ Tablets

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



NDC 0000-000-00

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



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0 00000 00000 0

LOT NO.

EXP.

: 915D7 FA CBP3-D

CODE AREA

STANDARD FORMAT

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

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

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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole	
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.	
Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain	
Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)	
Drug Facts (continued)	
Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Directions	
■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours	
14-Day Course of Treatment	
■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets	
Repeated 14-Day Courses (if needed)	
■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor	
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.	
Other information	
■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

Drug Facts (continued)

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

Questions or comments?
1-800-719-9260

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

Tips for Managing Heartburn

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

NDC 00000-000-00 **28 + 14 FREE** Treats Frequent Heartburn! Occurring 2 Or More Days a Week

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

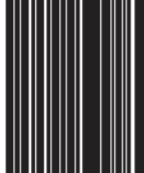
Omeprazole Delayed Release Tablets 20mg

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



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

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000000000



LOT NO.
EXP.
: 935D? FA CBP3-C

CODE AREA

STANDARD FORMAT

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

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

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Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Omeprazole 20 mg.....		Stop use and ask a doctor if	
Purpose Acid reducer		<ul style="list-style-type: none"> your heartburn continues or worsens you need to take this product for more than 14 days you need to take more than 1 course of treatment every 4 months you get diarrhea 	
Use		Directions	
<ul style="list-style-type: none"> treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect 		<ul style="list-style-type: none"> for adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 	
Warnings		14-Day Course of Treatment	
<ul style="list-style-type: none"> Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. 		<ul style="list-style-type: none"> swallow 1 tablet with a glass of water before eating in the morning take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor swallow whole. Do not chew or crush tablets 	
<ul style="list-style-type: none"> Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition. heartburn with lightheadedness, sweating or dizziness chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness frequent chest pain frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain 		Repeated 14-Day Courses (if needed)	
<ul style="list-style-type: none"> 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) 		<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. 	
		Other information	
		<ul style="list-style-type: none"> read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F) and protect from moisture 	

Drug Facts (continued)

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

Questions or comments?
1-800-719-9260

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

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

NDC 0000-000-00

Treats Frequent Heartburn!
Occurring 2 Or More Days a Week

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

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

LOT NO.
EXP.
: 915D7 FA CBP3-J

CODE AREA

STANDARD FORMAT

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

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



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Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	
Warnings Allergy alert: Do not use if you are allergic to omeprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)	
Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ swallow whole. Do not chew or crush tablets Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture	

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

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

Tips for Managing Heartburn

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

NDC 0000-000-00

3 PACK Three 14-day courses of treatment

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

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



CODE AREA

LOT NO.
EXP.
: 915D7 FA CBP3-A

STANDARD FORMAT

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

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

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Tips for Managing Heartburn

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

Triple Pack Three 14-day courses of treatment

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

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

Omeprazole Delayed Release Tablets 20mg
Acid Reducer

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

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

00-000-000-00

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CODE AREA

LOT NO.
EXP.
: 915D7 FA CBP3-G

Drug Facts

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

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

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

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking

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

Drug Facts (continued)

Stop use and ask a doctor if

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

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

Directions

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

14-Day Course of Treatment

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

Repeated 14-Day Courses (if needed)

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

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

Other information

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

Drug Facts (continued)

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

Questions or comments?
1-800-719-9260

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

STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed

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

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

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

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

FRONT PANEL

Peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 00000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



14 Tablets

: 91574 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 next purchase of
14 COUNT SIZE
"Store Brand" Omeprazole
Delayed Release Tablets 20 mg

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

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



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

12-5-14

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 0000-0000-00

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

 TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

14 Tablets

One 14-day course of treatment
1 BOTTLE INSIDE

: 915D5 FA CP3

BACK PANEL

SAVE \$X NOW!

Omeprazole Delayed Release Tablets 20 mg 14 Count

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

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.



12-5-14

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

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

FRONT PANEL

Peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 00000-000-00

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

**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



28 Tablets

Two 14-day courses of treatment

: 91530 FA CP3

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. **RETAILER:** This coupon will be redeemable for face value on specified products (plus a handling fee) 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**

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

Proposed Draft Labeling
NDA 22-032

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

FRONT PANEL

peel off coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

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

NDC 0000-000-00



**Omeprazole Delayed
Release Tablets 20mg**

Acid Reducer



28 Tablets

Two 14-day courses of treatment
2 BOTTLES INSIDE

: 915D6 FA CP3

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be 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**

12-5-14

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

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

FRONT PANEL

Peel off
coupon

Instant Redeemable Coupon - Expires XX-XX-XX

SAVE \$X NOW!
On This Purchase

NDC 00000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer



42 Tablets

Three 14-day courses of treatment

: 91555 FA CP3

BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. RETAILER: This coupon will be redeemable for face value on specified products (plus a handling fee) 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: NICH, PO Box 980036, El Paso, TX 79898-0036

COUPON NOT SUBJECT TO DOUBLING
Customer pays any sales tax.



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

12-5-14

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

FRONT PANEL

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

NDC 0000-000-00

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 Tablets

Three 14-day courses of treatment
3 BOTTLES INSIDE

915D7 FA CP3



BACK PANEL

SAVE \$X NOW!

MANUFACTURER'S COUPON EXPIRATION DATE XX/XX/XXXX

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

CONSUMER: Only one coupon is redeemable per purchase. **RETAILER:** This coupon will be 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 42 Count

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
06/11/2015