

Proposed Draft Labeling
NDA 209400
Omeprazole Delayed Release Orally
Disintegrating Tablets, 20 mg

Place tablet on tongue; tablet disintegrates, with or without water. Do not crush or chew tablets.
First two doses of a 14-day course of treatment.
Take 1 tablet every day for 14 days.
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

<p>6.5 pt Helvetica Black Cond.</p>	<p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Push tablet through foil Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p>	<p>6.5 pt Helvetica Black Cond.</p>	<p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Push tablet through foil Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p>
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5 pt Helvetica Bold Cond.

6 pt Helvetica Bold Cond.

6 pt Helvetica Medium

Proposed Draft Labeling
 NDA 209400
**Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 14 Tablets**

Drug Facts (continued)

Other information

Keep the carton, it contains important information.

Store at 20-25°C (68-77°F); keep product out of high heat and moisture.

Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopolone, ferric oxide, flavor, hydroxypropyl methylcellulose, hypromellose, polyethylene glycol, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate.

Drug Facts (continued)

Warnings

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

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

- warfarin, clopidogrel or clostazolol (blood-thinning medicines)
- 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 get diarrhea
- you develop a rash or joint pain

Directions

For adults 18 years of age and older

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

Repeated 14-Day Course (if needed)

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

14-Day Course of Treatment

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water.
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

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; this drug may take 1 to 4 days for full effect.

Warnings

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

Do not use if you have:

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

Ask a doctor before use if you have:

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

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

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

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you get diarrhea
- you develop a rash or joint pain

Purpose

Acid reducer

Active ingredient (in each tablet)

Omeprazole 20 mg

Drug Facts (continued)

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

Drug Facts (continued)

Questions or comments? 1-800-719-9286
 weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd.
 10 Hakkdima St, Yokneam 2069200, Israel

Batch No. _____
 EXP : XXX74 FA CJ

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

Read Drug Facts label on back before trying

FREE SAMPLE INSIDE
 (NOT FOR SALE)

NEW DOSAGE FORM!

Omeprazole

Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Melts in your mouth

Treats Frequent Heartburn!
 Occurring 2 or More Days a Week

2 TABLETS

Follow samples with a 14-day course of treatment

Tips for Managing Heartburn

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

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

FDA Approved

NDC 64239-XXX-07

Strawberry Flavor

Orally Disintegrating Tablets

Actual size

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 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

Place tablet on tongue; tablet disintegrates, with or without water. Do not crush or chew tablets. One 14-day course of treatment. Take 1 tablet every day for 14 days. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

6.5 pt Helvetica Black Cond.

5 pt Helvetica Bold Cond.

6 pt Helvetica Bold Cond.

6 pt Helvetica Medium

Omeprazole
Delayed Release Orally
Disintegrating Tablets 20 mg
acid reducer
Push tablet through foil
Dexcel Pharma Technologies Ltd.
10 Hakidma St. Yokneam 2069200,
Israel

Omeprazole
Delayed Release Orally
Disintegrating Tablets 20 mg
acid reducer
Push tablet through foil
Dexcel Pharma Technologies Ltd.
10 Hakidma St. Yokneam 2069200,
Israel

Omeprazole
Delayed Release Orally
Disintegrating Tablets 20 mg
acid reducer
Push tablet through foil
Dexcel Pharma Technologies Ltd.
10 Hakidma St. Yokneam 2069200,
Israel

Omeprazole
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Disintegrating Tablets 20 mg
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Israel

Omeprazole
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Disintegrating Tablets 20 mg
acid reducer
Push tablet through foil
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Israel

	<p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer</p> <p>Push tablet through foil</p> <p>Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p>	<p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer</p> <p>Push tablet through foil</p> <p>Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p>	<p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer</p> <p>Push tablet through foil</p> <p>Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p>
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4.5 pt Helvetica Bold Cond.			
5 pt Helvetica Bold Cond.			
5 pt Helvetica Medium			

Proposed Draft Labeling
NDA 209400
Omeprazole Delayed Release Orally
Disintegrating Tablets 20 mg
14 Tablets (Inner Carton)

Batch No.
EXP
: 1A974 00 VJ1

CODE AREA

<p>Drug Facts (continued)</p> <p>Warnings Do not use if you have: ● trouble or pain swallowing food, vomiting with blood, or bloody or black stools ● heartburn with lightheadedness, sweating or dizziness ● chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ● frequent chest pain These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have: ● had heartburn over 3 months. This may be a sign of a more serious condition ● frequent wheezing, particularly with heartburn ● unexplained weight loss ● nausea or vomiting ● stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking: ● warfarin, clopidogrel or clostazolol (blood-thinning medicines) ● prescription antifungal or anti-yeast medicines ● diazepam (anxiety medicine) ● tacrolimus or mycophenolate mofetil (immune system medicines) ● prescription antiretrovirals (medicines for HIV infection) ● methotrexate (arthritis medicine)</p> <p>Stop use and ask a doctor if: ● your heartburn continues or worsens ● you need to take this product for more than 14 days ● you develop a rash or joint pain ● you get diarrhea</p>	<p>Active Ingredient (in each tablet) Omeprazole 20 mg, Acid reducer</p> <p>Purpose Acid reducer</p> <p>Use ● treats frequent heartburn (occurs 2 or more days a week) ● not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings Do not use if you are allergic to omeprazole</p>
<p>Directions ● for adults 18 years of age and older ● this product is to be used once a day (every 24 hours), every day for 14 days ● it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</p> <p>1-Day Course of Treatment ● take 1 tablet before eating in the morning ● do not crush or chew tablets ● place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ● take every day for 14 days ● do not take more than 1 tablet a day ● do not use for more than 14 days unless directed by your doctor ● do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (if needed) ● you may repeat a 14-day course every 4 months ● do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>Other Information ● children under 18 years of age: ask a doctor before use; heartburn in children may sometimes be caused by a serious condition. ● read the directions and warnings before use ● keep the carton, it contains important information. ● store at 20-25°C (68-77°F); keep product out of high heat and moisture</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>
<p>Inactive ingredients alcohol, colloidal silicon dioxide, croscopolone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize starch, mannitol, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>

Drug Facts (continued)
Questions or comments? 1-800-719-9280.
Weekdays 7:30 AM to 5:00 PM EST

Made in Israel
Manufactured by:
Cexcel Pharma Technologies Ltd.,
10 Hakhinda St., Yokneam 2089200, Israel

NOT FOR RESALE

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

NDC 64239-XXX-01

Omeprazole

Delayed Release Orally Disintegrating Tablets 20 mg Acid Reducer

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

14 TABLETS
One 14-day course of treatment



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

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

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6 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

5-30-17

Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 14 Tablets

Batch No.
 EXP : 1Y974 FA CJ

CODE AREA

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg.....Acid reducer</p> <p>Purpose Use ■ treats frequent heartburn (occurs 2 or more days a week) 1 to 4 days for full effect</p> <p>Warnings Do not use if you have: trouble or pain swallowing food, vomiting with blood, or bloody or black stools heartburn with lightheadedness, sweating or dizziness chest or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or lightheadedness These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: frequent wheezing, particularly with heartburn had heartburn over 3 months. This may be a sign of a more serious condition Ask a doctor or pharmacist before use if you are taking: warfarin, clopidogrel or cilsastol (blood-thinning medicines) prescription antifungal or anti-yeast medicines diltiazem (heart medicine) tacrolimus or mycophenolate mofetil (immune system medicines) prescription antiretrovirals (medicines for HIV infection) Stop use and ask a doctor if: ■ your heartburn continues or worsens you need to take this product for more than 14 days you get diarrhea you develop a rash or joint pain</p>	<p>Drug Facts (continued)</p> <p>Directions for adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days it may take 1 to 4 days for full effect; some people get complete relief or symptoms within 24 hours</p> <p>14-Day Course of Treatment take 1 tablet before eating in the morning do not crush or chew tablets place the tablet on tongue, tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (if needed) you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F); keep product out of high heat and moisture</p> <p>Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize starch, mannitol, microcrystalline cellulose, polyene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>
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Drug Facts (continued)
Questions or comments? 1-800-719-9280;
 weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexcel Pharma Technologies Ltd.,
 10 Hakkalma St. Yokneam 2069200, Israel



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

NEW DOSAGE FORM!

NDC 64239-XXX-01

Omeprazole

Delayed Release Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Treats Frequent Heartburn!
 Occurring 2 or More Days a Week

14 TABLETS

One 14-day course of treatment



Tips for Managing Heartburn

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

MODIFIED FORMAT

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

5-26-17

Proposed Draft Labeling
 NDA 209400
**Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 14 Tablets**

Batch No.
 EXP
 : 1Y974 FA CJ

CODE AREA

<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Other information</p> <ul style="list-style-type: none"> children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. do not take for more than 14 days or more often than every 4 months unless directed by a doctor you may repeat a 14-day course every 4 months do not take this medicine with alcohol do not use for more than 14 days unless directed by your doctor do not take more than 1 tablet a day take every day for 14 days The tablets can also be swallowed whole with water. place the tablet on tongue; tablet disintegrates, with or without water. do not crush or chew tablets take 1 tablet before eating in the morning <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> symptoms within 24 hours it may take 1 to 4 days for full effect; some people get complete relief of this product is to be used once a day (every 24 hours), every day for 14 days for adults 18 years of age and older Directions <p>Warnings</p> <ul style="list-style-type: none"> not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect Use treats frequent heartburn (occurs 2 or more days a week) Omeprazole 20 mg.....Acid reducer <p>Active ingredient (in each tablet)</p> <p>Purpose</p>	<p>Drug Facts</p> <p>Warnings</p> <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 heartburn with lightheadedness, sweating or dizziness chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness frequent chest pain <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> had heartburn over 3 months. This may be a sign of a more serious condition recent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> warfarin, clopidogrel or clostazol (blood-thinning medicines) prescription antifungal or anti-yeast medicines diszepam (anxiety medicine) digoxin (heart medicine) tacrolimus or cyclosporine (immunosuppressant medicines) prescription antibiotics (medicines for HIV infection) methocarbamol (arthritis medicine) <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> your heartburn continues or worsens you need to take this product for more than 14 days you need to take more than 1 course of treatment every 4 months you get diarrhea you develop a rash or joint pain <p>Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopollose, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize meal, mannitol, sodium stearate, sodium lauryl sulfate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>
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Drug Facts (continued)
 Questions or comments? 1-800-719-9290.
 weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
Celexel Pharma Technologies, Ltd.
 10 Hakdama St, Yokneam 2069200, Israel



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

NEW DOSAGE FORM!

FDA Approved

NDC 64239-XXX-01

Omeprazole

Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Melts in your mouth
 Dissolves without water

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

14 TABLETS
 One 14-day course of treatment

Strawberry Flavor 

Orally Disintegrating Tablets Actual size

Tips for Managing Heartburn

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

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) **7 pt Helvetica Neue 57 Condensed**
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TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

5-26-17

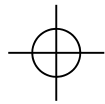
Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 28 Tablets

Omeprazole
 Delayed Release
 Orally Disintegrating Tablets 20 mg

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

Drug Facts (continued)
Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopolone, ferric oxide, flavor, hypromellose, hypromellose phtalate, maize maltoedextrin, mannitol, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST



CODE AREA

Batch No.
 EXP
 : 1Y930 FA C1

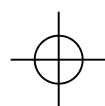
<p>Drug Facts</p> <p>Omeprazole 20 mg.....Acid reducer</p> <p>Active ingredient (in each tablet)</p> <p>Purpose</p> <p>Use</p> <p>■ treats frequent heartburn (occurs 2 or more days a week)</p> <p>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings</p> <p>Do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> trouble or pain swallowing food, vomiting with blood, or bloody or black stools heartburn with lightheadedness, sweating or dizziness chest or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness requent chest pain <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> had heartburn over 3 months. This may be a sign of a more serious condition heartburn with wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> warfarin, clopidogrel or cilostazol (blood-thinning medicines) prescription antifungal or anti-yeast medicines diazepam (anxiety medicine) digoxin (heart medicine) tacrolimus or mycophenolate mofetil (immune system medicines) prescription antiretrovirals (medicines for HIV infection) methotrexate (arthritis medicine) 	<p>Directions</p> <ul style="list-style-type: none"> ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F); keep product out of high heat and moisture
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	



Tips for Managing Heartburn

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

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



NEW DOSAGE FORM!

NDC 64239-XXX-02

Omeprazole
 Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Melts in your mouth

Treats Frequent Heartburn!
 Occurring 2 or More Days a Week

28 TABLETS

Two 14-day courses of treatment

Strawberry
 Flavor



Orally
 Disintegrating
 Tablets



Actual size

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 7.0 pt
- BULLETS:** 5 pt Square
- TELEPHONE #:** 6 pt Helvetica Neue 77 Bold Condensed
- HEAVY LINES:** 1.5 pt
- HAIRLINES:** 0.5 pt

Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 28 Tablets

Omeprazole
 Delayed Release
 Orally Disintegrating Tablets 20 mg

Drug Facts (continued)
Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopolone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltoedextrin, mannitol, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

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

Drug Facts

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

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

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

Do not use if you have:
 ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 ■ heartburn with **hightheadiness, sweating or dizziness**
 ■ chest or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness

Ask a doctor before use if you have:
 ■ had heartburn over 2 months. This may be a sign of a more serious condition
 ■ frequent wheezing, particularly with heartburn
 ■ unexplained weight loss
 ■ nausea or vomiting
 ■ stomach pain

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

Other information
 ■ store at 20-25°C (68-77°F); Keep product out of high heat and moisture
 ■ keep the carton. It contains important information.
 ■ read the directions and warnings before use

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

14-Day Course of Treatment
 ■ take 1 tablet before eating in the morning
 ■ do not crush or chew tablets
 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.

Repeated 14-Day Course (if needed)
 ■ take every day for 14 days
 ■ do not take more than 14 days unless directed by your doctor
 ■ do not take this medicine with alcohol

4 months unless directed by a doctor
 ■ 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 before use. Heartburn in children may sometimes be caused by a serious condition.

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

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

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 or symptoms within 24 hours

14-Day Course of Treatment
 ■ take 1 tablet before eating in the morning
 ■ do not crush or chew tablets
 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.

Repeated 14-Day Course (if needed)
 ■ take every day for 14 days
 ■ do not take more than 14 days unless directed by your doctor
 ■ do not take this medicine with alcohol

4 months unless directed by a doctor
 ■ 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 before use. Heartburn in children may sometimes be caused by a serious condition.

Other information
 ■ store at 20-25°C (68-77°F); Keep product out of high heat and moisture
 ■ keep the carton. It contains important information.
 ■ read the directions and warnings before use

CODE AREA

Batch No.
 EXP
 : 3Y530 FA C1



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

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

NEW DOSAGE FORM!

FDA Approved

NDC 64239-XXX-02

Omeprazole

Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Melts in your mouth
 Dissolves without water

Treats Frequent Heartburn!
 Occurring 2 or More Days a Week

28 TABLETS
 Two 14-day courses of treatment

Strawberry Flavor



Orally Disintegrating Tablets



Actual Size

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 7.0 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Proposed Draft Labeling
NDA 209400
Omeprazole Delayed Release Orally
Disintegrating Tablets 20 mg
42 Tablets**

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

Drug Facts (continued)

Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopolone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize malto-dextrin, mannitol, microcrystalline cellulose, polyethylene glycol, polyethylene glycol, sodium stearate, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST


CODE AREA

Batch No. _____
EXP _____
: 1Y955 FA C3

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Omeprazole 20 mg Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings Allergy alert: do not use if you are allergic to omeprazole Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: ■ had heartburn over 3 months. This may be a sign of a more serious condition ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain Ask a doctor or pharmacist before use if you are taking: ■ warfarin, clopidogrel or clostazolol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine)</p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if: ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets The tablets can also be swallowed whole with water. ■ place the tablet on tongue; tablet disintegrates, with or without water. take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor do not take this medicine with alcohol Repeat 14-Day Course (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ■ read the directions and warnings before use ■ keep the carton, it contains important information. ■ store at 20°-25°C (68°-77°F); keep product out of high heat and moisture</p>
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Omeprazole

Delayed Release
Orally Disintegrating Tablets 20 mg



Tips for Managing Heartburn

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

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

NDC 64239-XXX-03

NEW DOSAGE FORM!

Omeprazole

Delayed Release
Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth



Treats Frequent Heartburn!
Occurring 2 or More Days a Week

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 7.0 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
NDA 209400
Omeprazole Delayed Release Orally
Disintegrating Tablets 20 mg
42 Tablets

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

Drug Facts (continued)

Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscollon, cellulose, polyethylene glycol, povidone, ferric oxide, Havor, hypromellose, hypromellose phthalate, maize methoxypropyl, mannitol, microcrystalline cellulose, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Batch No. _____
EXP : 21/55 FA C1

CODE AREA

Drug Facts (continued)

Directions
For adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours
14-Day Course of Treatment
■ take 1 tablet before eating in the morning
■ do not crush or chew tablets
■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor
■ do not take this medicine with alcohol
■ 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 before use. 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); keep product out of high heat and moisture

Drug Facts

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

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

Stop use and ask a doctor if:
■ you get diarrhea ■ you develop a rash or joint pain
■ you are pregnant or breastfeeding, 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
■ heartburn with lightheadedness, sweating or dizziness
■ chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
■ frequent chest pain
These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have:
■ had heartburn over 3 months. This may be a sign of a more serious condition
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain
Ask a doctor or pharmacist before use if you are taking:
■ warfarin, clopidogrel or clostazolol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Omeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg



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

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

NEW DOSAGE FORM!

FDA Approved

NDC 64239-XXX-03

Omeprazole

Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

Melts in your mouth
Dissolves without water

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

42 TABLETS
Three 14-day courses of treatment

Strawberry Flavor 

Orally Disintegrating Tablets  Actual size

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 7.0 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally
 Disintegrating Tablets, 20 mg
 Bottle Label

<p>Other Information</p> <ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F); keep product out of high heat and moisture 	<p>Drug Facts</p> <p>Active ingredient Purpose (in each tablet) Omeprazole 20 mgAcid reducer</p> <p>Use ■ Treats frequent heartburn (occurs 2 or more days a week)</p> <p>■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.</p>	<p>Safety Feature - Do not use if printed seal under cap is broken or missing.</p> <p>This label does not contain full product information. See carton for complete information. Read warnings and directions on carton before use. Retain carton for reference.</p>	<p style="text-align: center;">NOT FOR RESALE</p> <p>Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg Acid Reducer</p> <p>Treats Frequent Heartburn! Occurring 2 or More Days a Week</p> <p>14 Tablets Strawberry Flavor One 14-day course of treatment</p>	<p>Manufactured by: Dexcel Pharma Technologies Ltd. 10 Hakidma St. Yokneam 2069200, Israel</p> <p>LOT EXP</p> <p>0000000000 0000000000</p>
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MODIFIED FORMAT

TYPE SIZES:
 TITLE: 8.5 pt Helvetica Bold Cond. Oblique
 HEADINGS: 7.5 pt Helvetica Bold Cond. Oblique
 TEXT: 6 pt Helvetica Medium Cond.
 LEADING: 6 pt
 BULLETS: 5 pt
 LINES: 0.75 pt

A | B | C | D | E | F | G | H



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

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

Drug Facts (continued)

- do not take more than 1 tablet a day
 - do not use for more than 14 days unless directed by your doctor
 - do not take this medicine with alcohol
- Repeated 14-Day Course (if needed)**
- you may repeat a 14-day course every 4 months
 - do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. 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); keep product out of high heat and moisture

Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST

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

FDA Approved
NEW DOSAGE FORM!

1 BOTTLE INSIDE NDC 64239-XXX-08

Omeprazole

Delayed Release Orally Disintegrating Tablets 20 mg

Acid Reducer
Treats Frequent Heartburn!
Occurring 2 or More Days a Week



14 Tablets
One 14-day course of treatment



LOT NO.
EXP.

Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

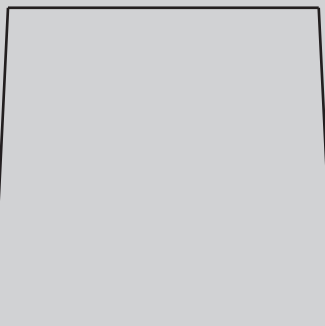
- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - heartburn with lightheadedness, sweating or dizziness
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent chest pain
- These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

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

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)



Drug Facts (continued)

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

Stop use and ask a doctor if:

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

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

Directions

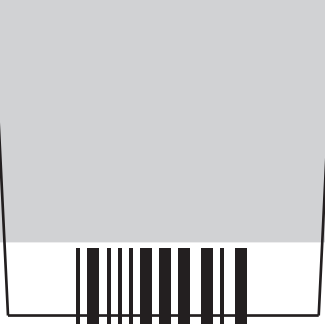
- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water.

The tablets can also be swallowed whole with water.

- take every day for 14 days



Proposed Draft Labeling
NDA 209400
Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg
14 Tablets

MODIFIED FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7.5 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) 7.5 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 67 Medium Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6.5 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg
 28 Tablets

MODIFIED FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7.5 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) 7.5 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 67 Medium Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6.5 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

A | B | C | D | E | F | G | H

Omeprazole
 Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Drug Facts (continued)
 Questions or comments?
 1-800-719-9260:
 weekdays 7:30 AM to 5:00 PM EST

2 BOTTLES INSIDE NDC 64239-XXX-09

NEW DOSAGE FORM!

Omeprazole
 Delayed Release
 Orally Disintegrating Tablets 20 mg
 Acid Reducer

Melts in your mouth

Treats Frequent Heartburn!
 Occurring 2 or More Days a Week

28 Tablets
 Two 14-day courses of treatment




Strawberry Flavor Actual size

Drug Facts

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

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

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

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

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

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LOT NO.
EXP.

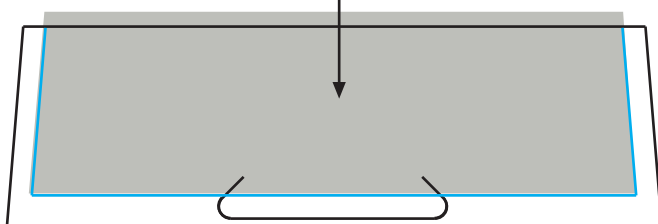
No Lacquer



No Lacquer



No Lacquer



A | B | C | D | E | F | G | H

Omeprazole

Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

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); keep product out of high heat and moisture

Inactive ingredients

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?
1-800-719-9260
weekdays 7:30 AM to 5:00 PM EST

3 BOTTLES INSIDE NDC 64239-XXX-10

NEW DOSAGE FORM!

Omeprazole

Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

Melts in your mouth

Treats Frequent Heartburn!
Occurring 2 or More Days a Week

42 Tablets
Three 14-day courses of treatment



Strawberry Flavor Actual size

FDA Approved

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.

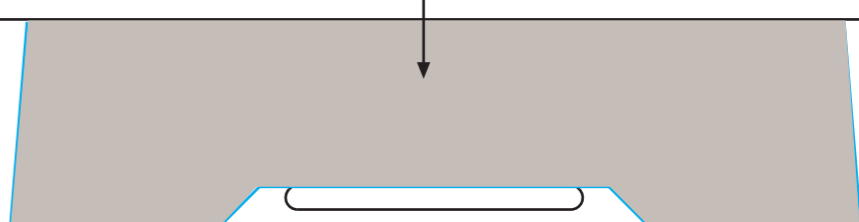


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Drug Facts

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

Use

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

Warnings

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

Do not use if you have:

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

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

Ask a doctor before use if you have:

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

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

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

Drug Facts (continued)

Stop use and ask a doctor if:

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

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

Directions


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

14-Day Course of Treatment

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

Repeated 14-Day Course (if needed)

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



No Lacquer

Proposed Draft Labeling
 NDA 209400
 Omeprazole Delayed Release Orally
 Disintegrating Tablets 20 mg
 42 Tablets

MODIFIED FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique

TITLE (continued): 7.5 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 67 Medium Condensed

LEADING: 6.5 pt

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

TELEPHONE #: 6.5 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt