

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

6.5 pt Helvetica Black Cond.

5 pt Helvetica Bold Cond.

6 pt Helvetica Bold Cond.

6 pt Helvetica Medium

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.

**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

**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.

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**Disintegrating Tablets 20 mg**  
acid reducer

**Push tablet through foil**  
Dexcel Pharma Technologies Ltd.  
10 Hakidma St. Yokneam 2069200,  
Israel

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**Push tablet through foil**  
Dexcel Pharma Technologies Ltd.  
10 Hakidma St. Yokneam 2069200,  
Israel

<p style="text-align: center;"><b>Omeprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 20 mg</b>  acid reducer</p> <p style="text-align: center;"><b>Push tablet through foil</b>  Dexcel Pharma Technologies Ltd.  10 Hakidma St. Yokneam  2069200, Israel</p>	<p style="text-align: center;"><b>Omeprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 20 mg</b>  acid reducer</p> <p style="text-align: center;"><b>Push tablet through foil</b>  Dexcel Pharma Technologies Ltd.  10 Hakidma St. Yokneam  2069200, Israel</p>	<p style="text-align: center;"><b>Omeprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 20 mg</b>  acid reducer</p> <p style="text-align: center;"><b>Push tablet through foil</b>  Dexcel Pharma Technologies Ltd.  10 Hakidma St. Yokneam  2069200, Israel</p>
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5.5 pt Helvetica Black Cond. \_\_\_\_\_

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  
: 2Y974 00 VJ

CODE AREA

**Drug Facts (continued)**  
**Questions or comments? 1-800-719-9260:**  
Weekdays 7:30 AM to 5:00 PM EST  
Made in Israel  
Manufactured by:  
Dexcel Pharma Technologies Ltd.,  
10 Hekindia St. Yokneam 2069200, Israel

<b>Drug Facts (continued)</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). <b>Directions</b> ■ for adults 18 years of age and older ■ take 1 tablet 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours ■ 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 <b>Repeated 14-Day Course (if needed)</b> ■ 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. <b>Other Information</b> ■ 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 <b>Inactive ingredients</b> amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, croscopollose, ferric oxide, flavor, hydroxypropyl methylcellulose, hypromellose, polyethylene glycol, sodium dodecyl sulfate, sodium lauryl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate	<b>Drug Facts</b> <b>Active ingredient (in each tablet)</b> Omeprazole 20 mg <b>Purpose</b> Acid reducer <b>Use</b> ■ 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 <b>Warnings</b> <b>Allergy alert:</b> do not use if you are allergic to omeprazole <b>Do not use if you have:</b> ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with hightheadedness, sweating or dizziness ■ chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness <b>Ask a doctor before use if you have:</b> These may be signs of a serious condition. See your doctor. ■ frequent chest pain ■ spreading to arms, neck or shoulders; or lightheadedness ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ stomach pain <b>Ask a doctor or pharmacist before use if you are taking:</b> ■ warfarin, ciprofloxacin or clobazepam (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ methotrexate (arthritis medicine) <b>Stop use and ask a doctor if:</b> ■ 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
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<b>NOT FOR RESALE</b>	<b>Safety Feature --</b> Do not use if printed tablet blister unit is open or torn.
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**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



0 00000 00000 0

**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

**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

5-26-17

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

Batch No.  
EXP  
: 1A794 FA CL

CODE AREA

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

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

**Drug Facts**

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

**Purpose**  
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  
■ 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 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, croscopollose, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize methylcellulose, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

**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  
■ headache with **lightheadedness, sweating or dizziness**  
■ chest or shoulder pain with shortness of breath; sweating; pain spreading to arm, neck or shoulder; or lightheadedness  
■ frequent chest pain  
These may be signs of a serious condition. See your doctor.

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

**Ask a doctor or pharmacist before use if you are taking:**  
■ warfarin, clopidogrel or clostazol (blood-thinning medicines)  
■ prescription antifungal or anti-yeast medicines  
■ dextroamphetamine (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



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



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



## STANDARD FORMAT

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**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**

## STANDARD FORMAT

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**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><b>Safety Feature</b> - Do not use if printed seal under cap is broken or missing. This label does not contain full product information. See carton for complete information. Read warnings and directions on carton before use. Retain carton for reference.</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose (in each tablet)</b></p> <p>Omeprazole 20 mg ..... Acid reducer</p> <p><b>Use</b> ■ Treats frequent heartburn (occurs <b>2 or more</b> 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><b>Other information</b></p> <p>■ 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><b>NOT FOR RESALE</b></p> <p><b>Omeprazole Delayed Release Orally Disintegrating Tablets</b> <b>20 mg</b> Acid Reducer</p> <p>Treats <b>Frequent Heartburn!</b> Occurring <b>2 or More Days a Week</b></p> <p><b>14 Tablets</b> Strawberry Flavor One 14-day course of treatment</p>	<p>Manufactured by: <b>Dexcel Pharma Technologies Ltd.</b> 10 Hakidma St. Yokneam 2069200, Israel</p> <p>LOT EXP</p> <p>000000000000 000000000000</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

No  
Lacquer

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

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

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

Tips for Managing Heartburn

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

FDA Approved

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



Strawberry Flavor



Actual size

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)

D-4

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

No  
Lacquer



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

**TYPE SIZES:**  
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**TITLE (continued):** 7.5 pt Helvetica Neue 77 Bold Condensed Oblique  
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**HEADINGS:** 8 pt Helvetica Neue 77 Bold Condensed Oblique  
**SUBHEADINGS:** 6 pt Helvetica Neue 77 Bold Condensed  
**TEXT:** 6 pt Helvetica Neue 67 Medium Condensed  
**LEADING:** 6.5 pt  
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**Omeprazole**  
Delayed Release  
Orally Disintegrating Tablets 20 mg  
Acid Reducer

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

LOT NO.  
EXP.

000000000000

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

**Purpose**  
Acid reducer

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

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

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

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

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

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

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

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

**14-Day Course of Treatment**  
■ take 1 tablet before eating in the morning ▶

**Drug Facts (continued)**  
■ 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.

**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 ▶

No  
Lacquer

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