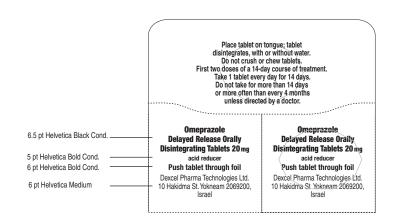
Proposed Draft Labeling NDA 209400 Omeprazole Delayed Release Orally Disintegrating Tablets, 20 mg



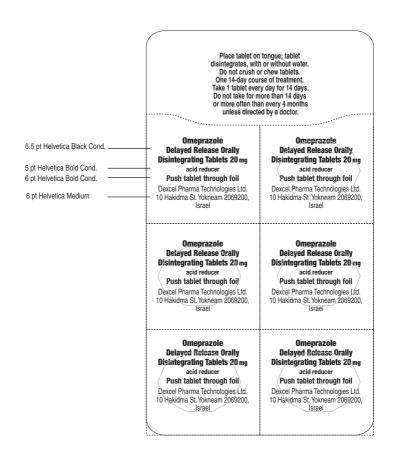
Proposed Draft Labeling NDA 209400 **Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg** 14 Tablets



MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Obli
(continued) 7 pt Helvetica Neue 57 Condensed HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Obliq SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed **TEXT: 6 pt Helvetica Neue 57 Condensed** BULLETS: 5 pt Square with 2 M'S spacing between statem 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. or current labeling information, please visit https://www.fda.gov/drugsatf



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

	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 SL Yolvneam 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 Hakkidma 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. Vokneam 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 Hakkidma St. Vokneam 2069200, Israel	Place tablet on tongue; tablet disintegrates, with or without water. Do not crush or chew tablets. One 14-day course of treatment. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.	Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Push tablet through foil Dexcel Pharma Technologies Ltd. 10 Hakidma St. Vokneam 2069/200, Israel
	Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Push tablet through foil Dexcel Pharma Technologies Ltd. 10 Hakkidma St. Vokneam 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. Vokneam 2069200, Israel
5.5 pt Helvetica Black Cond. 4.5 pt Helvetica Bold Cond. 5 pt Helvetica Bold Cond. 5 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

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 209400 **Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg** 14 Tablets (Inner Carton)

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

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Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd. Hakidma St. Yokneam 2069200, Israe

Inactive ingradients amino methacrylate copolymer, ascorbic sciol, cetyl alcohot, coloidas illond oldode, cospondorale, elimot obde, lävor, hypomellices, hypomellices, phibrialist, maiss maitoloestrin, manniol, microcrystalline cellulose, propylene glycol, allicon dioxide, sodium stearate, sodium fastavit unartet, sombilot, sucralose, sugar spheres, lalo; blanium loxidet, retethy dirate.

Other information

■ read the directions and warnings before use

■ keep the direction. It contains important information.

■ keep the 20-26°C (68-77°F); keep product out of high heat and moisture

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

d moutips nujesz qi.ecjeq pà s qocjot.
■ qo uot jeke tot mote tijeu 14 qaks ot mote otlen tijen ekety
■ yon may repeat a 14-day course ekety 4 moutips

Repeated 14-Day Course (if needed)

■ do not take this medicine with alcohol Table Table! Defore esting in the morning a faster ! table! Defore esting in the morning a faster ! table! Defore esting in the morning a passed with or withhout water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

The table!s can stop be swallowed whole with water.

14-Day Course of Treatment

■ 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

■ if nay take 1 to 4 days for full effect, some people get complète relief of

■ if nay take 1 to 4 days for full effect, some people get complète relief of Directions

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

Drug Facts (continued)

In the secretion and interest and are a decicines of medicines and interest an

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

■ srowscu bsin Endured or vorning 11

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Batch

Ask a doctor before use if you have:

■ instal statutum over 3 months. This may be a sign of a more serious condition
■ instal statutum over 3 months. This may be a sign of a more serious condition
■ installation when the most statutum of a more serious condition.
■ unacces crommitted.

Processors with lightheadedness, sweating or dizziness metaly or dizziness metaly or shoulder lost with lightheadedness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness metaly one of the special processors or sections or sec

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

DO NOT USE IT YOU NAVE: Allergy alert: do not use if you are allergic to omeprazole

To 4 days for full effect **Use** • Treats frequent heartbum (occurs <u>2 or more</u> days a week) • not intended for immediate relief of heartbum; this drug may take

Purpose Acid reducer

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

Drug Facts

NOT FOR RESALE

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



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

Strawberry

Orally Disintegrating 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

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

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

Facts (continued)

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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 Hakidma St. Yokneam 2069200, Israel

Inactive ingredients amino methacylate copolymer, ascorbic acid, cetyl
acionol, cobloida silicon doxide, crospovidone, ferric oxide, flavor,
hypomellose, hypomellose propylene glybod, silicon doxide, sodium stearate,
microcyasiline ceilinose, propylene glybod, silicon doxide, sodium stearate,
sodium steary fumarate, sorbitol, sucralose, sugar spheres, talc, titanium
dioxide, theithyl citrate

Other information

■ read the directions and warnings before use

■ keep the directions for the mode of the mode o

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

Repeated 14-Day Course (if needed)

■ do not take this medicine with alcohol
■ do not take this medicine with alcohol ■ take every day for 14 days

■ do not take more than 1 tablet a day

■ take 1 tablet before eating in the morning ■ to not rush or tews bablets

■ place the tablet on tongue; tablet disintagrates, with or without water.

The tablets can also be swallowed whole with water.

The tablets can also be swallowed whole with water.

14-Day Course of Treatment

■ 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 ■ if nay take 1 to 4 days for full effect, some people get complete relief of nicections

lf **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).

nund racts (continued)

Stop use and ask a doctor if:

we not not obsect bits product for more than 14 day.

we not not obsect bits product for more than 14 day.

we not not be not be not be not be almost every 4 months.

we not get diarrhea

- tacrolimus or mycophenolate mofetil (immune system medicines)
 prescription antiretrovirals (medicines for HIV infection)
 methodrexate (arthrifis medicine) ■ digoxin (heart medicine)

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

 mandamacist before use if you are taking

 mandam, clopidogrei or cilostatori (blode-trinining medicines)

 prescription antifungal or anti-yeast medicine

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- nausea or vomiting stomach pain
- Ask a doctor before use if you have:

 installation over 3 months. This may be a sign of a more serious condition

 installation over 3 months. This may be a sign of a more serious condition

 installation which the serious provided in the serious provided in the serious committee.

- These may be signed to a serious capacitics.

 In first with ill platheadedness, sweating or dizziness a breath, with lightheadedness spreading to arms, neck or shoulders; or lightheadedness afterent chest pain.

 In these may be signs of a serious condition. See your doctor.

 Are a Academic and the first pain and a serious condition. See your doctor.
- trouble or pain swallowing food, vomiting with blood, or bloody or Do not use if you have:

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

TO 4 days for full effect

Use •• Treats frequent hearthum (occurs $\underline{2}$ or \underline{more} days a week) •• not intended for immediate relief of hearthum; this drug may take $\underline{1}$ to A have for full effect

Purpose Acid reducer

Active ingredient (in each tablet)

Drug Facts

NDC 64239-XXX-01



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



<u>Umeprazole</u>

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

Strawberry Flavor

Orally Disintegrating Tablets



- 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

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



HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Obli SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

BULLETS: 5 pt Square with 2 M'S spacing between state TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

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



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
HEADY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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



STANDARD FORMAT

TYPE SIZES:

TITE: 9 pt Helvetica Neue 77 Bold Condensed Oblique TITLE: 9 pt Helvetica Neue 77 Bold Condensed (continued) 8 pt Helvetica Neue 77 Bold Condensed (continued) 8 pt Helvetica Neue 77 Bold Condensed Obliques SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Conde LEADING: 6.5 and 7.0 pt

BULLETS: 5 pt Square

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

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



STANDARD FORMAT

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

Three 14-day courses of treatment

42 TABLETS

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

Orally

Disintegrating Tablets

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 209400 Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg 42 Tablets** L 10 Hakidma St. Yokneam 2069200, Israel Manufactured by: Dexcel Pharma Technologies Ltd. Made in Israel Questions or comments? 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST iyypromeliose phithalate, maize maliodexthin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbibl, sucraiose, sugar spheres, talci, titanium dioxide, trietiny citrate Inactive ingredients amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose ■ keep the cardon, it contains important information.

■ store at 2.0-25°C (68-77°F); keetp product out of high heat and moisture ■ methotrexate (arthritis medicine) ■ prescription antiretrovirals (medicines for HIV infection) ■ tacrolimus or mycophenolate mofetil (immune system m ■ read the directions and warnings before use ■ digoxin (heart medicine) аізхерат (алхіету теаісіпе) ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazona (proviety medicine) culiquen may sometimes be caused by a serious condition. ■ children under 18 years of age: ask a doctor before use. Heartburn in Delayed Release Orally Disintegrating Tablets 20 mg ■ 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 Yak a doctor or pharmacist before use if you are taking: ■ stomach pain Repeated 14-Day Course (if needed) ■ nuexblained weight loss Ask a doctor before use if you have:

In the incurrent wheesing, particularly with heartburn

In trequent wheesing, particularly with heartburn ■ qo uot take this medicine with alcohol ■ place the tablet on nongue; tablet disninegrates, with or without water.

The tablets can also be awallowed whole with water.

■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not take more than 1 tablet a day
■ do not take more than 14 days unless directed by your doctor.
■ do not take the for more than 14 days unless directed by your doctor.
■ do not take this medicine with all chosts. These may be signs of a serious condition. See your doctor. to arms, neck or shoulders; or lightheadedness

Trequent chest pain ■ do not crush or chew tablets ■ heartburn with lightheadedness, sweating or dizziness
■ chest or shoulder pain with shortness of breath; sweating; pain spreading ■ take 1 tablet before eating in the morning 14-Day Course of Treatment ■ for edults 18 years of age and older

In finally take 1 to 4 days for full effect; some people get complète relief of

whithous of 4 days for full effect; some people get complète relief of

14,1391 foures of Teorèmos black stools ■ trouble or pain swallowing food, vomiting with blood, or bloody or Do not use if you have: Allergy alert: do not use if you are allergic to omeprazole Warnings If pregnant or breast-feeding, sak 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). 1 to 4 days for full effect ■ treats frequent heartburn (occurs <u>2 or more</u> days a week) ■ not intended for immediate relief of heartburn; this drug may take ■ you geed to take this product for more than 14 days

■ you need to take more than 1 course of treatment every 4 months **Purpose** Acid reducer Stop use and ask a doctor if:

your heartburn continues or worsens Active ingredient (in each tablet) Drug Facts **Drug Facts** (continued) Tips for Managing Heartburn
■ Do not lie flat or bend over after eating
■ Do not wear tight-fitting clothing around Safety Feature -Do not use if printed tablet the stomach blister unit is open or torn. ■ 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!** NDC 64239-XXX-03 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 Disintegrating Tablets Three 14-day courses of treatment 711 1 STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Neue 77 Bold Condensed Obliq 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

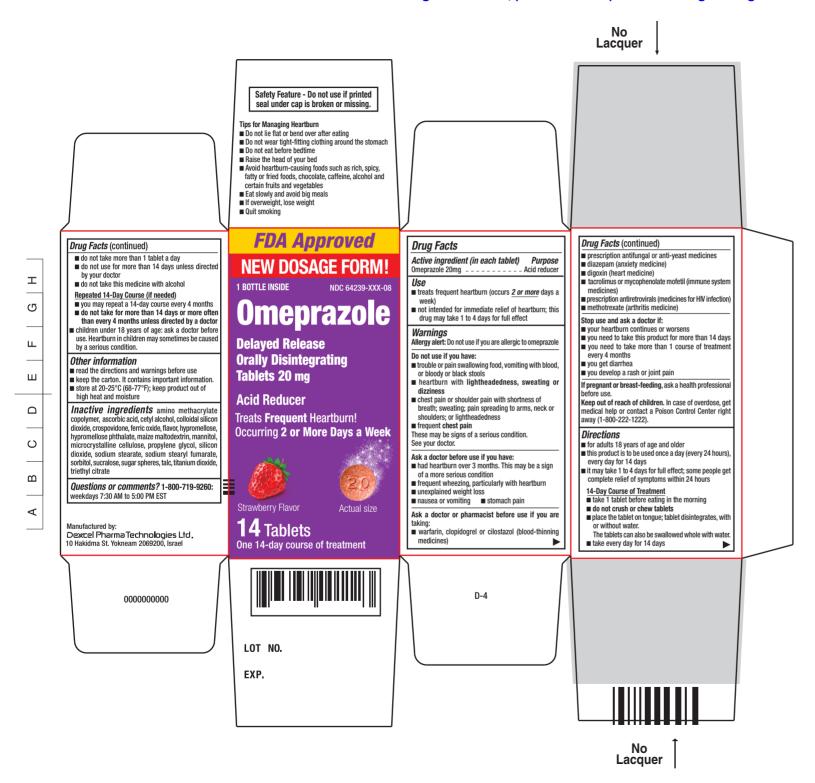


MODIFIED FORMAT

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



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

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

MODIFIED FORMAT

HEAVY LINES: 1.5 pt HAIRLINES: 0.5 pt

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 **BULLETS: 5 pt Square with 2 M'S spacing between statements** TELEPHONE #: 6.5 pt Helvetica Neue 77 Bold Condensed

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

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MODIFIED FORMAT

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TITLE: 0 pt Helvetica Neue 77 Bold Condensed (continued); 7.5 pt Helvetica Neue 57 Condensed HEADINGS: 8 pt Helvetica Neue 57 Bold Condense SUBHEADINGS: 8 pt Helvetica Neue 77 Bold Condense SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condense LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing betwee TELEPHONE #: 6.5 pt Helvetica Neue 77 Bold CONHEADINGS: 6.5 pt Helvetica Neue 77 Bold CONHEADINGS: 5 pt Helvetica Neue 77 Bold CONHEADINGS: 5 pt Helvetica Neue 77 Bold CONHEADINGS: 0.5 pt