

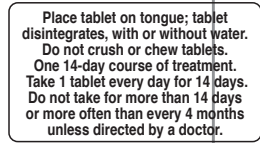
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214278Orig1s000

LABELING

5.5 pt Helvetica Neue Bold Cond.



6.5 pt Helvetica Neue Black Cond.

5.7 pt Helvetica Neue Medium

5.5 pt Helvetica Neue Bold Cond.

Esomeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel 1. SEPARATE AT PERFORATION. 2. PEEL AT ARROW.	Batch No.00000000 Exp YYYY/MM START HERE Batch No.00000000 Exp YYYY/MM PEEL PEEL	Esomeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel 1. SEPARATE AT PERFORATION. 2. PEEL AT ARROW.
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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.	Batch No.00000000 Exp YYYY/MM PEEL	Esomeprazole Delayed Release Orally Disintegrating Tablets 20 mg acid reducer Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel 1. SEPARATE AT PERFORATION. 2. PEEL AT ARROW.



STANDARD FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Bold Cond. Oblique
TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique
(continued) 7.5 pt Helvetica Medium Cond.

HEADINGS: 8 pt Helvetica Bold Cond. Oblique
SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique

TEXT: 6 pt Helvetica Medium Cond.

LEADING: 6.5 pt

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

TELEPHONE #: 6.5 pt Helvetica Bold Cond.

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

DIMENSIONS: 117 x 17 x 90 mm



STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Bold Cond. Oblique
TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique
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HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

DIMENSIONS: 117 x 17 x 90 mm

Drug Facts (continued) Inactive ingredients acetone, alcohol, amino methacrylate copolymer, ascorbic acid, benzyl alcohol, cetyl alcohol, colloidal silicon dioxide, croscopolone, FD&C blue no. 1, aluminum lake, FD&C blue no. 2, aluminum lake, havor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polyvinylpyrrolidone 80, pregelatinized starch, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucrose, sugar spheres, talc, titanium dioxide, traccetin, triethyl citrate (Questions or comments? 1-800-XXX-XXXX weekdays XXX AM to XXX PM EST)	Tips for Managing Heartburn ■ Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables. ■ Eat slowly and do not eat big meals. ■ Do not eat late at night or just before bedtime. ■ Do not lie flat or bend over soon after eating. ■ Raise the head of your bed. ■ Wear loose-fitting clothing around your stomach. ■ If you are overweight, lose weight. ■ If you smoke, quit smoking.
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No
Lacquer →

← No Lacquer

Tips for Managing Heartburn ■ Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables. ■ Eat slowly and do not eat big meals. ■ Do not eat late at night or just before bedtime. ■ Do not lie flat or bend over soon after eating. ■ Raise the head of your bed. ■ Wear loose-fitting clothing around your stomach. ■ If you are overweight, lose weight. ■ If you smoke, quit smoking.	Drug Facts (continued) Inactive ingredients acetone, alcohol, amino methacrylate copolymers, ascorbic acid, benzyl alcohol, cetyl alcohol, colloidal silicon dioxide, croscopolldone, FD&C blue no. 1, aluminum lake, FD&C blue no. 2 aluminum lake, havor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polyacrylate 80, pregelatinized starch, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, traccetin, triethyl citrate (Questions or comments? 1-800-XXX-XXXX) weekdays XXX AM to XXX PM EST
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No
Lacquer →

← No Lacquer

Esomeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

42 TABLETS
Three 14-day courses of treatment
May take 1 to 4 days for full effect

Melts in your mouth
Dissolves without water

Treats Frequent Heartburn!

Wildberry Flavor

Drug Facts
Active ingredient (in each tablet) Purpose
Esomeprazole 20 mg Acid reducer
(Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)

Uses
■ 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 esomeprazole
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 a prescription drug. Acid reducers may interact with certain prescription drugs.
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

Drug Facts (continued)
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
■ adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ may take 1 to 4 days for full effect
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.

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
■ store in the original package

Batch No EXP

Back Panel:
NDC 64239-XXX-04
Melts In Your Mouth
Treats Frequent Heartburn!
24 HR
Dissolves without water
Melts in your mouth
Acid Reducer
Delayed Release
Orally Disintegrating Tablets 20 mg
42 TABLETS
Three 14-day courses of treatment
May take 1 to 4 days for full effect
Wildberry Flavor
Actual size
Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
Eat slowly and do not eat big meals.
Do not eat late at night or just before bedtime.
Do not lie flat or bend over soon after eating.
Raise the head of your bed.
Wear loose-fitting clothing around your stomach.
If you are overweight, lose weight.
If you smoke, quit smoking.

Side Panel:
Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd.
10 Hakdima St. Yokneam 2089200, Israel

Bottom Panel:
Safety Feature – Do not use if printed tablet blister unit is open or torn.
KEEP THE CARTON.
IT CONTAINS IMPORTANT INFORMATION.

STANDART FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Bold Cond. Oblique
TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique
(continued) 7.5 pt Helvetica Medium Cond.

HEADINGS: 8 pt Helvetica Bold Cond. Oblique
SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique
TEXT: 6 pt Helvetica Medium Cond

LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6.5 pt Helvetica Bold Cond.

HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

DIMENSIONS: 120 x 58 x 94 mm

Drug Facts Active ingredient (in each tablet) Esomeprazole 20 mg. ----- Acid reducer (Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)	
Purpose Acid reducer	
Uses ■ 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 esomeprazole 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 a prescription drug. Acid reducers may interact with certain prescription drugs.	
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	
Drug Facts (continued) 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 ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ may take 1 to 4 days for full effect 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.	
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 ■ store in the original package	

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

TELEPHONE #: 6.5 pt Helvetica Bold Cond.

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
10/20/2020 03:34:03 PM