

ESOMEPRAZOLE- esomeprazole tablet, orally disintegrating, delayed release
Dexcel Pharma Technologies Ltd

Esomeprazole Delayed Release Orally Disintegrating Tablets, 20 mg

Drug Facts

Active ingredient (in each tablet)

Esomeprazole 20 mg

(Each delayed-release 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

- Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

If an allergic reaction occurs, stop use and seek medical help right away.

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

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 Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor 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

Inactive ingredients

acetone, alcohol, amino methacrylate copolymer, ascorbic acid, benzyl alcohol, cetyl alcohol, colloidal silicon dioxide, croscopovidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, flavor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polysorbate 80, pregelatinized starch, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, 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.

NDC 64239-112-02

MELTech™

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

14 TABLETS

One 14-day course of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

000000000

14 TABLETS
 One 14-day course of treatment
 May take 1 to 4 days for full effect

Metts in your mouth
 Dissolves without water

Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

Esomeprazole

Treats Frequent Heartburn!
 24 HR

Compare to the active ingredient
 in Nexium® 24HR

NDC 64239-112-02

MELTech™
 Melts In Your Mouth

Wildberry Flavor

Actual size

■ 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.

■ 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. ■ If you smoke, quit smoking.

TIPS FOR MANAGING HEARTBURN

NEED THE CARTON, IT CONTAINS IMPORTANT INFORMATION.
 *This product is not intended for distribution outside the United States.
 NDC 64239-112-02

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

D-55

Made in Israel
 Manufactured by:
 Otsuka Pharmaceutical Co., Ltd.
 10 Hakoma St., Yokohama 226-8502, Japan

Batch No. _____
 EXP _____

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Esomeprazole 20 mg (Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)</p> <p>Purpose Acid reducer</p> <p>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</p> <p>Warnings Allergy alert: ■ Do not use if you are allergic to esomeprazole. ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>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</p> <p>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 a prescription drug. Acid reducers may interact with certain prescription drugs.</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</p>	<p>Drug Facts (continued)</p> <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> <p>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</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 ■ store in the original package</p> <p>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, flavor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, poly sorbate 80, pregelatinized starch, silicon dioxide, sodium stearate, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, triethyl citrate</p>
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Drug Facts (continued)
 Questions or comments? 1-800-XXX-XXXX | weekdays 9AM to 5PM EST

MELTech™

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

28 TABLETS

Two 14-day courses of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

Tip 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 a big meal.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Roll 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)

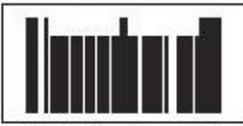
Inactive ingredients: acacia, alcohol, and/or methacrylic copolymer, ascorbic acid, benzyl alcohol, croscarmellose, colloidal silicon dioxide, croscarmellose, FD&C blue no. 1, xanthan gum, FD&C blue no. 2, aluminum hydroxide, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polyethylene glycol, pregelatinized starch, silicon dioxide, sodium starch glycolate, sodium stearoyl fumarate, sorbitol, sucrose, sugar spheres, talc, titanium dioxide, triacetin, white clay.

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NDC 64239-112-04
Weekdays 9:00 AM to 5:00 PM EST

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This product is not manufactured or distributed by GSK, GlaxoSmithKline or its affiliates.

Melt in Your Mouth
Manufactured by
Orion Pharmaceuticals, Inc.,
101 Williams St., Toronto, Ontario, Canada



KEEP THE CARTON
TIGHTLY CLOSED TO PROTECT FROM LIGHT AND MOISTURE.
Safety Feature - Do not use if expired date and lot number are not visible.

Esomeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

D-08

Drug Facts		Drug Facts (continued)
Active ingredient (in each tablet) Esomeprazole 20 mg.	Purpose Acid reducer	<ul style="list-style-type: none"> if you need to take this product for more than 14 days if you need to take more than 1 course of treatment every 4 months if you get diarrhea if you develop a rash or joint pain
Uses to treat frequent heartburn (occurs 2 or more days a week)		<p>Directions</p> <ul style="list-style-type: none"> adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days take every day for 14 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
Warnings Allergy alert: Do not use if you are allergic to esomeprazole. Some people can have severe skin reactions. Symptoms may include: - skin redness - hives - rash If an allergic reaction occurs, stop use and seek medical help right away.		<p>Important 14-Day Course of Treatment:</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>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 store in the original package
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 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 sweating, 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. - pregnant or breastfeeding. Tell your doctor if you are pregnant or breastfeeding.		
Stop use and ask a doctor if: - your heartburn continues or worsens		

NDC 64239-112-04
MELTech™

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

42 TABLETS

Three 14-day courses of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

NDC 64239-112-05

MELTech™

Melts in Your Mouth

FREE SAMPLE

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

2 TABLETS

First 2 doses of a 14-day course of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

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.
- If you smoke, quit smoking.

- 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.

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2 TABLETS
Delayed Release Orally Disintegrating Tablets 20 mg Acid Reducer
Esomeprazole
Wildberry Flavor
 Melts in your mouth
 Dissolves without water
 May take 1 to 4 days for full effect
 First 2 doses of a 14-day course of treatment
 Actual size
Treats Frequent Heartburn!
 24 HR
Compare to the active ingredient in Nexium® 24HR.
NDC 64239-112-05
MELTech™
 Melts In Your Mouth
FREE SAMPLE

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

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION.
 This product is not to be used if the printed tablet is open or torn.
 NDC 64239-112-05

NOT FOR SALE

D-56

Made in Israel
 Manufactured by
 Chiesol Pharmaceuticals Ltd.,
 10 Hakdama St., Tel-Aviv 6109200, Israel

Batch No
 EXP

Drug Facts		Drug Facts (continued)
Active ingredient (in each tablet) Esomeprazole 20 mg	Purpose Acid reducer	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).
(Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)		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
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. ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If an allergic reaction occurs, stop use and seek medical help right away.	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.
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	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
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	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, flavor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polyorbital 80, pregelatinized starch, silica dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, tristyl chloride

Drug Facts (continued)
 1-800-XXX-X-XXXX | weekdays 9XX AM to XXX PM EST
 Questions or comments?

NDC 64239-112-07
MELTech™

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

14 TABLETS

One 14-day course of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

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.
- If you smoke, quit smoking.

- 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.

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

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION.
This product is not for oral use or distribution by GSK, distributor of Nexium® 24HR.

D-55

Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Esomeprazole 20 mg (Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trifluorhydrate)	Purpose Acid reducer	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).	
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		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.	
Warnings Allergy alert: ■ Do not use if you are allergic to esomeprazole. ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If an allergic reaction occurs, stop use and seek medical help right away.		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	
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.		Inactive ingredients ascorbic acid, amino methacrylate copolymer, ascorbic acid, benzyl alcohol, castyl alcohol, colloidal silicon dioxide, croscarmellose, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, flavor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, polyorbital 80, pregelatinized starch, silica dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, triethyl citrate	
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			

Made in Israel
Manufactured by
Dexced Pharmaceuticals Ltd.,
10 Hakdima St. Yokneam 2089200, Israel

Batch No
EXP

Drug Facts (continued)
Questions or comments? 1-800-XXX-X-XXX | weekdays XXX AM to XXX PM EST

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

28 TABLETS

Two 14-day courses of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

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, anilino methacrylate copolymer, ascorbic acid, benzyl alcohol, ethyl alcohol, cellulose, silica dioxide, croscollon, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, flavor, hypromellose, hydroxypropyl cellulose, isopropyl alcohol, menthyl, microcrystalline cellulose, non-filled starch, polyacrylate 60, pregelatinized starch, silicon dioxide, sodium stearyl succinate, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? 1-800-XXX-XXXX weekdays XXXAM to XXX PM EST

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28 TABLETS

Two 14-day courses of treatment
May take 1 to 4 days for full effect

Melts in your mouth
Dissolves without water

Acid Reducer

Delayed Release
Orally Disintegrating Tablets 20 mg

Esomeprazole

Treats Frequent Heartburn!
24 HR

Compare to the active ingredient
in Nexium® 24HR*

MeltTech™
Melts in Your Mouth

Batch No. EXP

MDC04290-11 20 8

Made in Israel
Manufactured by:
Omesol Pharma Technologies Ltd.,
10 Hildana St. Tel Aviv 6106000, Israel

*This product is not manufactured
or distributed by OTC, Hildana/OT
Nexium® 24HR

Esomeprazole

Delayed Release
Daily Disintegrating Tablets 20 mg

Acid Reducer



IT CONTAINS IMPORTANT INFORMATION.
KEEP THE CARTON.

Save time - Do not eat or drink
for 1 hour until you are better.

Batch No. EXP

D-28

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Esomeprazole 20 mg. Acid reducer</p> <p>Purpose Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole (meq/gm) in 45 minutes</p> <p>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.</p> <p>Warnings Allergy alert: ■ Do not use if you are allergic to esomeprazole. ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If an allergy reaction occurs, stop use and seek medical help right away.</p> <p>Do not use if you have: ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with light-colored stools, 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.</p> <p>Ask a doctor before use if you have ■ bad 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 a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens</p>	<p>Drug Facts (continued)</p> <p>■ 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 dizziness ■ you develop a rash or joint pain</p> <p>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</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 ■ store in the original package</p>
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NDC 64239-112-09

MELTech™

Melts in Your Mouth

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

42 TABLETS

Three 14-day courses of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

NDC 64239-112-10

MELTech™

Melts in Your Mouth

FREE SAMPLE

Compare to the active ingredient in Nexium® 24HR*

*Treats **Frequent** Heartburn! 24HR*

Esomeprazole

Delayed Release

Orally Disintegrating Tablets 20 mg

Acid Reducer

Melts in your mouth

Dissolves without water

2 TABLETS

First 2 doses of a 14-day course of treatment

May take 1 to 4 days for full effect

Wildberry Flavor

Actual size

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolates, 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.
- If you smoke, quit smoking.

- 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.

Actual size

Wildberry Flavor

24 HR

2 TABLETS

May take 1 to 4 days for full effect

First 2 doses of a 14-day course of treatment

Metts in your mouth

Dissolves without water

Acid Reducer

Delayed Release

Orally Disintegrating Tablets 20 mg

Esomeprazole

Treats Frequent Heartburn!

Compare to the active ingredient in Nexium® 24HR*

NDC 64239-112-10

MELTECH™ Melts In Your Mouth

FREE SAMPLE

NOT FOR SALE

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION.

It is a product of a manufacturer or distributor of the drug.

Made in Israel

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

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D-55

Drug Facts	Drug Facts (continued)
<p>Active ingredient (in each tablet) Esomeprazole 20 mg (Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)</p> <p>Purpose Acid reducer</p> <p>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</p> <p>Warnings Allergy alert: ■ Do not use if you are allergic to esomeprazole. ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>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.</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 a prescription drug. Acid reducers may interact with certain prescription drugs.</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</p>	<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> <p>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</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 ■ store in the original package</p> <p>Inactive ingredients acetone, alcohol, amino methacrylate copolymer, ascorbic acid, benzyl alcohol, cetylalcohol, colloidal silicon dioxide, croscopolidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, flavor, hypromellose, hypromellose phthalate, isopropyl alcohol, mannitol, microcrystalline cellulose, modified starch, poly sorbate 80, pregelatinized starch, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, triethyl citrate</p>

Made in Israel
Manufactured by:
Cesca® Pharma Technologies Ltd.,
10 Hakkma St., Yokneam 2089200, Israel

Batch No
EXP

Drug Facts (continued)

Questions or comments? 1-800-XXX-XXXX | weekdays XXX AM to XXX PM EST

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ESOMEPRAZOLE

esomeprazole tablet, orally disintegrating, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64239-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Esomeprazole (UNII: N3PA6559FT) (ESOMEPRAZOLE - UNII:N3PA6559FT)	Esomeprazole	20 mg

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST) (UNII: 8LDD2V82F5)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	11mm
Flavor	RASPBERRY (Wildberry)	Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64239-112-07	2 in 1 CARTON	04/12/2024	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:64239-112-08	2 in 1 CARTON	04/12/2024	
2		2 in 1 CARTON		
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:64239-112-09	3 in 1 CARTON	04/12/2024	
3		2 in 1 CARTON		
3		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:64239-112-10	1 in 1 CARTON	04/12/2024	
4		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:64239-112-02	2 in 1 CARTON	04/12/2024	
5		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:64239-112-03	2 in 1 CARTON	04/12/2024	
6		2 in 1 CARTON		
6		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:64239-112-04	3 in 1 CARTON	04/12/2024	
7		2 in 1 CARTON		
7		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:64239-112-05	1 in 1 CARTON	04/12/2024	
8		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA214278	04/12/2024	

Labeler - Dexcel Pharma Technologies Ltd (533597626)

Establishment

Name	Address	ID/FEI	Business Operations
Dexcel Pharma Technologies Ltd		533597626	manufacture(64239-112)

