

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

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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Esomeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

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

Melts in your mouth
Dissolves without water

Treats Frequent Heartburn!
24 HR

Compare to the active ingredient in Nexium® 24HR*

Melts in Your Mouth
MELTECH™

NDC 64239-112-02

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

IMPORTANT INFORMATION.
*This product is not intended
to be used for Nexium® 24HR.



D-55

Made in Israel
Manufactured by:
Chesed Pharma Technologies Ltd.,
10 Hakoma St., Yokneam 208600, 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	
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	■ this product is to be used once a day (every 24 hours), every day for 14 days	
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.		■ may take 1 to 4 days for full effect	
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		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	
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		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	
Ask a doctor or pharmacist before use if you are: ■ taking a prescription drug. Acid reducers may interact with certain prescription drugs.		■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.	
Stop use and ask a doctor if: ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain		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 acelone, 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	

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 on the back 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: acetic acid, alcohol, and/or methacrylic acid copolymer, ascorbic acid, benzyl alcohol, cetyl alcohol, colloidal silicon dioxide, croscarmellose, FD&C blue no. 1, xanthan gum, FD&C blue no. 2, aluminum hydroxide, hydroxypropyl methylcellulose, hydroxypropyl starch, 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, xanthan gum.

© 2013 Watson Pharmaceuticals, Inc.
NDC 64239-112-04
Weekdays 9 AM to 5 PM EST

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This product is manufactured and filled by GSK, distributed by Watson, Inc.

Melt in your mouth! Manufactured by Watson Pharmaceuticals, Inc., 101 Williams St., Toronto, ON M5X 1C3, Canada

Batch No: _____ EXP: _____

MELTech™ Melt in Your Mouth

24 HR

Treats Frequent Heartburn!

Compare to the active ingredient in Nexium® 24HR.

Delayed Release
Orally Disintegrating Tablets 20 mg

Melts in your mouth
Disolves without water

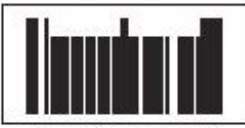
28 TABLETS

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

Willberry Flavor

Acid Reducer

NDC 64239-112-04



KEEP THE CARTON
IT CONTAINS IMPORTANT INFORMATION.

Safety Feature - Do not use if expired date either before or after the expiration date.

Esomeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

D-28

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) and is intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.		<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 may take 1 to 4 days for full effect <p>14-Day Course of Treatment:</p> <ul style="list-style-type: none"> take 1 tablet before eating in the morning do not crush or chew tablets place the tablet on tongue; tablet disintegrates, with or without water The tablets can also be swallowed whole with water. take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor do not take this medicine with alcohol <p>Important 14-Day Course (if needed):</p> <ul style="list-style-type: none"> you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>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
Warnings Allergy alert: Do not use if you are allergic to esomeprazole. See warnings if you may cause severe skin reactions. Symptoms may include: skin redness or blisters on face. 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 shoulder; or lightheadedness or 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 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		

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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Actual size

Wildberry Flavor



2 TABLETS
 First 2 doses of a 14-day course of treatment
 May take 1 to 4 days for full effect

Melts in your mouth
Dissolves without water

Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

FREE SAMPLE



Treats Frequent Heartburn!

Compare to the active ingredient
in Nexium® 24HR.

NDC 64239-112-05

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 printed on the back of
the unit is 24 HR.

NOT FOR SALE

D-56

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

Batch No
EXP

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.
 ■ 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.

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

Inactive ingredients
 acetone, alcohol, amlo 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, polyisobutyl methacrylate, polyethylene glycol, polyethylene glycol
 sorbitol, polyethylene glycol, polyethylene glycol, polyethylene glycol,
 sodium lauryl sulfate, sorbitol, sucralose, sugar spheres, talc, titanium
 dioxide, triacetin, triethyl citrate

Drug Facts (continued)
Questions or comments? 1-800-XXX-X-XXXX | weekdays 9AM to 5PM EST

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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14 TABLETS
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

Melts in your mouth
Dissolves without water

Compare to the active ingredient
in Nexium® 24HR*

Treats Frequent Heartburn!
24 HR

ESOMEPRAZOLE

Wildberry Flavor

Actual size

MELTech™
 Melts In Your Mouth™

NDC 64239-112-07



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 use in the
 U.S. or distributed by GSK, distributor of
 Nexium 24 HR.



D-55

Drug Facts		Drug Facts (continued)
Active ingredient (in each tablet) Esomeprazole 20 mg	Purpose Acid reducer	<p>Directions ■ adults 18 years of age and older</p> <ul style="list-style-type: none"> ■ 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>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p>
(Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole magnesium trifluorhydrate)		
Uses	<ul style="list-style-type: none"> ■ 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	<p>Allergy alert:</p> <ul style="list-style-type: none"> ■ 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. 	
Do not use if you have:	<ul style="list-style-type: none"> ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain <p>These may be signs of a serious condition. See your doctor.</p>	
Ask a doctor before use if you have	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ taking a prescription drug. Acid reducers may interact with certain prescription drugs. 	
Stop use and ask a doctor if	<ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain 	
		<p>Other information ■ read the directions and warnings before use</p> <ul style="list-style-type: none"> ■ 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>Inactive ingredients acsone, alcohol, amino methacrylate copolymer, ascorbic acid, benzyl alcohol, cetyl 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, polyorbale 80, pregelatinized starch, silica dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triacetin, triethyl citrate</p>

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

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

Batch No
 EXP

NDC 64239-112-08

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

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, hydroxyethylcellulose, isopropyl alcohol, menthyl, microcrystalline cellulose, non-filled starch, polyacrylate 60, pregelatinized starch, silicon dioxide, sodium stearyl succinate, sodium stearoyl fumarate, sorbitol, stearates, 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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Actual size

28 TABLETS

Melts in your mouth
Dissolves without water

Acid Reducer

Delayed Release
Orally Disintegrating Tablets 20 mg

Treats Frequent Heartburn!
24 HR

Compare to the active ingredient in Nexium® 24HR*

MELTech™ Melts In Your Mouth

May take 1 to 4 days for full effect

Two 14-day courses of treatment

MD-04-29-11-20-8

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

*The product is not manufactured or distributed by OTC, JarrowPharm, or Meltech 24HR



Esomeprazole
Delayed Release
Orally Disintegrating Tablets 20 mg
Acid Reducer

D-28

Drug Facts

Active ingredient (in each tablet)
Esomeprazole 20 mg. Acid reducer
Each delayed-release orally disintegrating tablet corresponds to 22.3 mg esomeprazole (meq/gm) in 45 mg (hydrate)

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 allergy 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 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.

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

Drug Facts (continued)

■ 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

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 (1-800-325-1222).

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



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



24 HR

2 TABLETS

First 2 doses of a 14-day course of treatment
May take 1 to 4 days for full effect

Wildberry Flavor

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

FREE SAMPLE

Melts in Your Mouth



NOT FOR SALE

KEEP THE CARTON. IT CONTAINS
IMPORTANT INFORMATION.
It is printed on an inner cover or
side of the box, distributor or
manufacturer 24 HR.

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

Drug Facts

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

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

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

Drug Facts (continued)

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

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

Batch No
EXP

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)

