Treats Frequent Heartburn

24 Hour Lansoprazole
Delayed Release Orally Disintegrating Tablets 15 mg
Acid Reducer

• May take 1 to 4 days for full effect

14 TABLETS
One 14-day course of treatment

Avoid eating, smoking, or drinking anything other than water for at least 15 minutes after you place the tablet in your mouth. Melts in your mouth.

Strawberry Flavor

Dissolved without water

Keep out of reach of children.

Keep the carton and package insert. They contain important information.

Questions or comments? 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST.

Not for Resale

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
14 Tablets (Inner Carton)
New Dosage Form!

24 Hour Lansoprazole
Delayed Release Orally Disintegrating Tablets 15mg

Acid Reducer
May take 1 to 4 days for full effect

14 TABLETS
ONE 14-DAY COURSE OF TREATMENT

Drug Facts

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg..................Acid Reducer

Inactive ingredients
ascorbic acid, cetyl alcohol, colloidal silicon dioxide,
Dissolves without water
polysorbate 80, propylene glycol, sodium stearyl fumarate,
polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate,

May take 1 to 4 days for full effect
although some people get complete
it may take 1 to 4 days for full effect, although some people get complete

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

10 Hakidma Street, Yokneam 2069200, Israel

Manufactured by:

Compare to the active ingredient in Prevacid® 24 HR*
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

28 TABLETS
TWO 14-DAY COURSES OF TREATMENT

New Dosage Form!
Melts in your mouth

Drug Facts
Compare to the active ingredient in Prevacid® 24 HR®

Use

Lansoprazole 15 mg.........................................................................Acid Reducer

Do not use if you are allergic to lansoprazole
Allergy alert:

Keep out of reach of children.

Questions or comments?
Ask a doctor before use if you have

Published by

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets

Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel
Made in Israel

5-16-17
Reference ID: 4188168

5-16-17
Reference ID: 4188168
Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
42 Tablets

New Dosage Form!

Compare to the active ingredient in Prevacid® 24 HR®

Treats Frequent Heartburn

Melt in your Mouth

1 24 Hour Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

42 TABLETS

Three 14-Day Courses of Treatment

STANDARD FORMAT

Type Sizes:

Title: 9 pt Helvetica Neue 77 Bold Condensed Oblique
Title (continued): 8 pt Helvetica ... 6.8 pt

Bullets: 5 pt Square

Telephone #: 6 pt Helvetica Neue 77 Bold Condensed

Heavy Lines: 1.5 pt

Hairlines: 0.5 pt

Reference ID: 4188168
Lansoprazole
Delayed Release Orally Disintegrating Tablets 15 mg

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

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg.........................................................................Acid Reducer

Inactive ingredients
maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Compare to the active ingredient in Prevacid® 24 HR*

Other information

If pregnant or breast-feeding, ask a doctor before use.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Keep out of reach of children.

In 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 for more than 14 days unless directed by your doctor.

You need to take this product for more than 14 days if your heartburn continues or worsens.

Ask a doctor before use if you have had heartburn over 3 months. This may be a sign of a more serious condition.

Take 1 tablet before eating in the morning.

Do not take more than 1 tablet a day.

Place the tablet on the tongue; tablet disintegrates, with or without water.

Take every day for 14 days.

Adapted to the active ingredient in Prevacid® 24 HR.

Dosage Form:
Orally Disintegrating Tablets 15 mg

Leads to incomplete heartburn relief even with a single dose of 15 mg even if needed.

Dissolves without water

Dissolves in mouth faster than other formulations

Some doses dissolve in the mouth faster than others.

Drug Facts

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg.........................................................................Acid Reducer

Inactive ingredients
maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Compare to the active ingredient in Prevacid® 24 HR*

New Dosage Form!
Orally Disintegrating Tablets 15 mg

24 Hour
Lansoprazole
Delayed Release Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Disappears without water

MELtech™ Melts in Your Mouth

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
28 Tablets

Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel
Made in Israel

5-16-17
Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Proposed Draft Labeling

NDA 208025

Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
42 Tablets

5-16-17

Drug Facts

Active ingredient (in each tablet) Purpose

Lansoprazole 15 mg..................................................Acid Reducer

Use

Directions

1. Place tablet on tongue; tablet disintegrates, with or without water.
2. Do not swallow tablet whole or rinse with water.

14-Day Course of Treatment

• You may repeat a 14-day course every 4 months

Other information

1. Children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
2. Do not use for more than 14 days unless directed by your doctor.
3. Do not use for more than 14 days or more often than every 4 months.
4. Do not use for more than 1 course of treatment every 4 months.
5. Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Allergy alert:

Do not use if you are allergic to lansoprazole.

Do not use:

• If you develop a rash or joint pain
• If your heartburn continues or worsens
• If heartburn causes you to lose weight or have trouble breathing
• If you need to take more than 1 course of treatment every 4 months

If you have any of the following symptoms, see your doctor:

• Fever or cold symptoms (including sore throat or runny nose)
• Chickenpox
• Cough that lasts more than 2 or more days a week
• Difficulty swallowing or pain when swallowing
• Unexplained weight loss
• Chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders
• Chest pain
• Frequent stomach pain
• Stomach or abdominal pain that is constant or frequent
• Nausea or vomiting
• Unexplained bleeding
• Unexplained changes in color or smell of your stools

Other medicines_RXed:

• Do not take this medicine with alcohol
• Do not use for more than 14 days unless directed by your doctor

Drug Interactions:

• Do not use this medicine with other antacids
• Do not use this medicine with prescription antifungal or anti-yeast medicines
• Do not use with theophylline
• Do not use with methotrexate
• Do not use with warfarin

Other Drug Facts:

• This product is to be used once a day (every 24 hours), every day for 14 days.
• It may take 1 to 4 days for full effect, although some people get complete relief sooner.

May take 1 to 4 days for full effect

New Dosage Form!

Melts in your mouth

Dissolves without water

Drug Facts

Inactive ingredients

ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, magnesium stearate, methacrylate copolymer, methylparaben, propylparaben, sodium lauryl sulfate, sodium starch glycolate, sucrose, talc, titanium dioxide, xanthan gum

Questions or comments?

Ask a doctor or pharmacist before use if you are taking other drugs that may interact with this medicine.

In case of overdose, get medical help or call 1-800-719-9260:

MELtech

In Your Mouth

Manufactured by:

[Address]

10 Hakidma Street, Yokneam 2069200, Israel

This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Manufactured by:

[Address]

10 Hakidma Street, Yokneam 2069200, Israel

This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Manufactured by:

[Address]

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Manufactured by:

[Address]

10 Hakidma Street, Yokneam 2069200, Israel

This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.
Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
14 Tablets

NEW DOSAGE FORM!

Strawberry Flavor

24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

May take 1 to 4 days for full effect

14 TABLETS

ONE 14-DAY COURSE OF TREATMENT

Directions

1. Take 1 tablet before eating in the morning.
2. Place the tablet on the tongue; tablet disintegrates, with or without water.
3. Do not chew or crush tablets.
4. Do not use for more than 14 days unless directed by a doctor.

Other Information

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg Acid Reducer

Use

- Do not use if you are allergic to lansoprazole
- Do not use if you are taking methotrexate (arthritis medicine)
- Do not use if you are taking theophylline (asthma medicine)
- Do not use if you develop a rash or joint pain
- Do not use if you have diarrhea
- Do not use if you are taking prescription antifungal or anti-yeast medicines
- Do not use if you are taking atazanavir (medicine for HIV infection)

Keep the carton and package insert. They contain important information.

Directions

- Take as directed.
- Do not use for more than 14 days unless directed by your doctor.
- This product is to be used once a day (every 24 hours), every day for 14 days.
- It may take 1 to 4 days for full effect, although some people get complete relief faster.
- The tablets can also be swallowed whole with water.
- Do not crush or chew tablets.
- This product is not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.
- Do not use for more than 14 days unless directed by your doctor.

Warnings

- This product is not a treatment for heartburn due to acid reflux disease.
- Do not use for more than 14 days unless directed by your doctor.
- Do not use if you are taking methotrexate (arthritis medicine).
- Do not use if you develop a rash or joint pain.
- Do not use if you have diarrhea.
- Do not use if you are taking prescription antifungal or anti-yeast medicines.
- Do not use if you are taking atazanavir (medicine for HIV infection).

Interactions

- Do not use if you are taking methotrexate (arthritis medicine).
- Do not use if you develop a rash or joint pain.
- Do not use if you have diarrhea.
- Do not use if you are taking prescription antifungal or anti-yeast medicines.
- Do not use if you are taking atazanavir (medicine for HIV infection).

Precautions

- Do not use if you are allergic to lansoprazole.
- Do not use if you are taking methotrexate (arthritis medicine).
- Do not use if you develop a rash or joint pain.
- Do not use if you have diarrhea.
- Do not use if you are taking prescription antifungal or anti-yeast medicines.
- Do not use if you are taking atazanavir (medicine for HIV infection).

Storage

- Store at 20-25°C (68-77°F).
- Protect product from moisture.
- Keep out of reach of children.
Delayed Release
Orally Disintegrating Tablets 15 mg

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

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

Lansoprazole
Acid Reducer

New Dosage Form!
24 Hour

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Treats Frequent Heartburn

Melts in your mouth
Dissolves without water
Child-resistant

208025
5-16-17
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Treats Frequent Heartburn

New Dosage Form!

24 Hour

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer
• May take 1 to 4 days for full effect

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Melts in your mouth

Value 2 Pack

Strawberry Flavor

Other information
Ask a health professional before use. If pregnant or breast-feeding, ask a health professional before use.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Drug Facts

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg Acids Reducer

Directions
Take 1 tablet before eating in the morning. Place the tablet on tongue; tablet disintegrates, with or without water. Do not chew or swallow whole.

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
28 Tablets

5-16-17
Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel
Made in Israel

May take 1 to 4 days for full effect

Use
This product is to be used once a day (every 24 hours), every day for 14 days.

Acid Reducer
Treats Frequent Heartburn

Revised 14-Day Course (if needed)

Repeated 14-Day Course (if needed)

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Do not use
Stop use and ask a doctor if you develop a rash or joint pain
your heartburn continues or worsens
you get diarrhea
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 have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

This product is not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect, although some people get complete relief in 1 to 3 days.

Do not use methotrexate (arthritis medicine) unless directed by a doctor.

You may repeat a 14-day course every 4 months. Keep the carton and package insert. They contain important information.

Store at 20-25°C (68-77°F) protect product from moisture.

May take 1 to 4 days for full effect

Reference ID: 4188168
New Dosage Form! 24 Hour Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Acid Reducer
■ May take 1 to 4 days for full effect

42 TABLETS THREE 14-DAY COURSES OF TREATMENT

Compare to the active ingredient in Prevacid® 24 HR*

Drug Facts

Lansoprazole 15 mg.........................................................................Acid Reducer

Directions
Take 1 tablet before eating in the morning, place the tablet on tongue; tablet disintegrates, with or without water.
Take every day for 14 days. It may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
Do not take more than 1 tablet a day
Do not use for more than 14 days unless directed by your doctor
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
Please do not use this medicine with alcohol
You develop a rash or joint pain
Your heartburn continues or worsens
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
This product is to be used once a day (every 24 hours), every day for 14 days
If you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
If pregnant or breast-feeding, in case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)
If you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Dosage Form
Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Active ingredients
Lansoprazole

Inactive ingredients
ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate

Uses
Use for frequent heartburn

Warnings
Do not use if you are allergic to lansoprazole
Allergy alert: Do not use if you are allergic to lansoprazole
Do not use if you are taking prescription antifungal or anti-yeast medicines
Do not use if you are taking tacrolimus or mycophenolate mofetil (immune system medicines)
Do not use if you are taking warfarin (blood-thinning medicine)
Do not use if you are taking digoxin (heart medicine)
Do not use if you are taking methotrexate (arthritis medicine)
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
If pregnant or breast-feeding, in case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)
Keep out of reach of children.

Proposed Draft Labeling  
NDA 208025  Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg  42 Tablets

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

May take 1 to 4 days for full effect
Orally Disintegrating Tablets 15 mg
Delayed Release
Lansoprazole
42 TABLETS
Acid Reducer
Treats Frequent Heartburn

Value 3 Pack

Made in Israel

Manufactured by:

Reference ID: 4188168
Lansoprazole
Delayed Release
Orally Disintegrating Tablets, 15 mg
28 Tablets

May take 1 to 4 days for full effect

New Dosage Form!
Melts in your mouth
Dissolves without water

Buy One 14 Count,
Get One 14 Count Free!

Get One 14 Count Free!

Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg

28 TABLETS
TWO 14-DAY COURSES
OF TREATMENT

Directions
Take 1 tablet before eating in the morning.
Place the tablet on the tongue;
it disintegrates, with or without 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.
You may repeat a 14-day course every 4 months.

Warning:
If you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools,
stop use and ask a doctor.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets

STOP USE AND ASK A DOCTOR IF
You develop a rash or joint pain
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

Revised 14-Day Course (if needed)

28 TABLETS
TWO 14-DAY COURSES
OF TREATMENT

DRUG FACTS

LANSOPRAZOLE 15 mg ..................................................................... Acid Reducer

Use
For treatment of frequent heartburn in adults.

Warnings
Do not use if you are allergic to lansoprazole.
Allergy alert:
Do not use if you have had an allergic reaction to this drug or to
any of its components.

Ask a doctor before use if you have
• liver disease
• severe stomach ulcers
• heart disease
• angina
• recent surgery
• skin lesions
• frequent wheezing
• frequent or severe heartburn
• nausea or vomiting
• stomach pain

Other information
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.

Other ingredients
Inactive ingredients:
maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Keep the carton and package insert. They contain important information.

Store at 20–25°C (68–77°F).
Protect product from moisture.

Reference ID: 4188168
Lansoprazole
Delayed Release
Orally Disintegrating Tablets, 15 mg
28 Tablets

**Acid Reducer**

May take 1 to 4 days for full effect

<table>
<thead>
<tr>
<th>Active ingredient (in each tablet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole 15 mg</td>
<td>Acid Reducer</td>
</tr>
</tbody>
</table>

**Warnings**

- Do not use if you are allergic to lansoprazole
- Do not use if you are pregnant or breast-feeding
- Keep out of reach of children
- Do not use for more than 14 days unless directed by your doctor

**Directions**

1. Place the tablet on your tongue; it disintegrates, with or without water.
2. Take once daily for 14 days.
3. Do not take more than 1 tablet a day.
4. Do not use for more than 14 days unless directed by your doctor.

**Storage**

- Store at 20-25°C (68-77°F)
- Keep product out of high heat and humidity
- Protect product from moisture

**Inactive ingredients**

- Maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate,

**Questions or comments?**

Ask a doctor or pharmacist before use if you are taking any prescription antifungal or anti-yeast medicines.

**Precautions**

- Avoid using this product if you are taking tacrolimus or mycophenolate mofetil (immune system medicines).
- Avoid using this product if you are taking methotrexate (arthritis medicine).

**Additional Information**

- This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

**Manufacturer**

10 Hakidma Street, Yokneam 2069200, Israel

Made in Israel

Reference ID: 4188168
Lansoprazole
Delayed Release
Orally Disintegrating Tablets
15 mg

New Dosage Form!
Melts in Your Mouth
Dissolves without Water

Drug Facts
Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg.........................................................................Acid Reducer

Warnings
Allergy alert: do not use if allergic to lansoprazole

Use
May take 1 to 4 days for full effect

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Keep the carton and package insert. They contain important information.

Keep out of reach of children.
In case of overdose, get medical help or call 1-800-719-9260.

Questions or comments? Call 1-800-719-9260.

STANDARD FORMAT
TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica ... 6.8 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 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
28 Tablets

5-16-17
Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel
Made in Israel

8U130 FA C5-P

Reference ID: 4188168
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Treats Frequent Heartburn

New Dosage Form! 24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

28 TABLETS
TWO 14-DAY COURSES OF TREATMENT

Compare to the active ingredient in Prevacid® 24 HR®

Bonuses! + 14 Free

Refer to package insert for complete information.

MELTech™ Melts in Your Mouth

Drug Facts
Lansoprazole 15 mg.........................................................................Acid Reducer

Inactive ingredients: maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate,

Keep out of reach of children.

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

Stop use and ask a doctor if

I you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

I heartburn spreads to arms, neck or shoulders; or lightheadedness

I chest pain or shoulder pain with shortness of breath; sweating; pain

I frequent chest pain

I frequent wheezing, particularly with heartburn

I nausea or vomiting

I vomiting with blood

I chest pain over 3 months. This may be a sign of a more serious condition.

I if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

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

I have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

I if you are taking prescription antifungal or anti-yeast medicines

I tacrolimus or mycophenolate mofetil (immune system medicines)

I theophylline (asthma medicine)

I methotrexate (arthritis medicine)

I other heartburn medicines; this drug may take 1 to 4 days for full effect

I unless directed by a doctor

I children may sometimes be caused by a serious condition.

I do not use for more than 14 days unless directed by your doctor

I do not crush or chew tablets

I do not take more than 1 tablet a day

I do not take for more than 14 days or more often than every 4 months

I do not take with alcohol

I treat frequent heartburn

I not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect, although some people get complete relief. It may be first used for 1 to 2 days to see if it helps to relieve heartburn.

I may take 1 to 4 days for full effect

I may take 1 to 4 days for full effect, although some people get complete relief.

I may take 1 to 4 days for full effect

I unless directed by a doctor

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

I do not use if printed tablet blister unit is open or torn.

I Stop use and ask a doctor if

I May take 1 to 4 days for full effect

I unless directed by a doctor

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

Drugs that may interact with this medicine:

I other heartburn medicines

I prescription antifungal or anti-yeast medicines

I tacrolimus or mycophenolate mofetil (immune system medicines)

I theophylline (asthma medicine)

I methotrexate (arthritis medicine)

I other drugs likely to cause heartburn

Ascorbic acid, iron, mineral supplements, and others may decrease the effect of this medicine.

Adults 18 years of age and older

This product is to be used once a day (every 24 hours), every day for 14 days

Place the tablet on tongue; tablet disintegrates, with or without water.

Take every day for 14 days

Take 1 tablet before eating in the morning

Two 14-Day Courses of Treatment

Use

I Delayed Release

I Lansoprazole

I Orally Disintegrating Tablets 15 mg

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

I Keep the carton and package insert. They contain important information.

I Reference ID: 4188168

Batch No. CODE AREA 8U130 FA C5-R
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
42 Tablets

New Dosage Form!

Melts in your mouth
Dissolves without water

Compare to the active ingredient in Prevacid® 24 HR*

14 Tablets Free

Drug Facts
Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg Acid Reducer

Warnings
Do not use
- if you are allergic to lansoprazole
- if you have had heartburn over 3 months. This may be a sign of a more serious condition.
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Do not use if you are taking methotrexate (arthritis medicine), warfarin (blood-thinning medicine), digoxin (heart medicine), theophylline (asthma medicine), or medications that make you a little more sensitive to the sun. If you have any of these medications, talk to your doctor before you use this medicine.

Ask a doctor before use if you have
- stomach pain
- chest pain
- heartburn with spreading to arms, neck or shoulders; or lightheadedness
- unexplained weight loss
- stomach pain
- liver disease
- your heartburn continues or worsens
- you develop a rash or joint pain
- frequent heartburn (occurs more than twice a week)
- heartburn with chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent or black stools
- liver disease
- unexplained weight loss
- stomach pain
- heartburn with chest pain

Do not use if taking warfarin (blood-thinning medicine), digoxin (heart medicine), theophylline (asthma medicine), or medications that make you a little more sensitive to the sun.

Drug Interactions
- Do not take this medicine with alcohol
- Take this medicine only as directed. Do not take for more than 14 days or more often than every 4 months

Repeated 14-Day Course (if needed)

Stop use and ask a doctor if
- you need to take this product for more than 14 days
- you develop a rash or joint pain
- your heartburn continues or worsens
- you have unexplained weight loss
- you have trouble or pain swallowing food, vomiting with blood, black stool

Missed Doses
- Take every day for 14 days
- Do not repeat a course of treatment until after 4 months.

Inactive ingredients
- maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate,
- sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Reading the directions, warnings and package insert before use

Read the directions, warnings and package insert before use

Keep the carton and package insert. They contain important information.
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

May take 1 to 4 days for full effect

New Dosage Form!
Orally Disintegrating Tablets 15 mg

Treats Frequent Heartburn

24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer
May take 1 to 4 days for full effect

42 TABLETS
TREAS 14-DAY COURSES OF TREATMENT

Melts in your mouth
Dissolves without water

Bonus Size! 14 Free

Keep the carton and package insert. They contain important information.

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

5-16-17
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel
Made in Israel
8U155 FA C5-P

Reference ID: 4188168
Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
42 Tablets

Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Directions
Take 1 tablet before eating in the morning. The tablets can also be swallowed whole with water.

Melts in your mouth
Dissolves without water

Drug Facts
Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg..................................................Acid Reducer

Warnings
Stop use and ask a doctor if
- you develop a rash or joint pain
- your heartburn continues or worsens
- you develop black stools. These may be signs of a serious condition. See your doctor.
- you get diarrhea
- 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 have trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- you have heartburn with chest pain
- you have chest pain
- you have frequent wheezing, particularly with heartburn
- you have unexplained weight loss
- you develop pain in your chest
- you have frequent heartburn (occurs 3 to 4 days a week)
- you have not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Do not use
- if you are allergic to lansoprazole
- if you are allergic to any of the ingredients in this tablet

Ask a doctor before use if you have
- liver disease
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain in the jaw or neck
- nausea or vomiting
- frequent heartburn
- frequent chest pain
- frequent pulmonary problems

Precautions
- Do not use for more than 14 days unless directed by your doctor
- Repeated 14-Day Course (if needed)
- you may repeat a 14-day course every 4 months
- Do not use for prescription antifungal or anti-yeast medicines
- Do not use for digoxin (heart medicine)
- Do not use for tacrolimus or mycophenolate mofetil (immune system medicines)
- Do not use for atazanavir (medicine for HIV infection)

Additional Warnings
- Proprietary Name Warning
- Do not use if printed tablet blister unit is open or torn.
- Do not crush or chew tablets
- Keep the carton and package insert.

Overdose
In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Proprietary Name Warning
This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Manufactured by:
10 Hakidma Street, Yokneam 2069200, Israel

Questions or comments?
1-800-719-9260:
Melt in your mouth
Melts in your mouth
Dissolves without water

Additional Warnings
- This product is a prescription medicine.
- Keep out of the reach of children.
- Use as directed.
- Do not use for anyone younger than 18 years of age without talking to a doctor.

Proprietary Name Warning
This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Manufactured by: 10 Hakidma Street, Yokneam 2069200, Israel

Questions or comments?
1-800-719-9260:
How Lansoprazole delayed release orally disintegrating tablets Treats Your Frequent Heartburn
Lansoprazole delayed release orally disintegrating tablets stops acid production at the source – the pumps that release acid into the stomach. Lansoprazole delayed release orally disintegrating tablets is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking Lansoprazole delayed release orally disintegrating tablets
Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole delayed release orally disintegrating tablets in the morning before eating. Lansoprazole is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take Lansoprazole delayed release orally disintegrating tablets every day for 14 days to treat your frequent heartburn.

Who Should Take Lansoprazole delayed release orally disintegrating tablets
Adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

Who Should NOT Take Lansoprazole delayed release orally disintegrating tablets
People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take Lansoprazole delayed release orally disintegrating tablets
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.

When to Take Lansoprazole delayed release orally disintegrating tablets Again
You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.
Warnings and When to Ask Your Doctor

Allergy alert: Do not use if you are allergic to lansoprazole

Do not use
- If you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- Liver disease
- Had heartburn over 3 months. This may be a sign of a more serious condition.
- 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
- Frequent wheezing, particularly with heartburn
- Unexplained weight loss
- Nausea or vomiting
- Stomach pain

Ask a doctor or pharmacist before use if you are taking
- Warfarin (blood-thinning medicine)
- Prescription antifungal or anti-yeast medicines
- Digoxin (heart medicine)
- Theophylline (asthma medicine)
- Tacrolimus or mycophenolate mofetil (immune system medicines)
- Atazanavir (medication for HIV infection)
- Methotrexate (arthritis medicine)

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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.

Clinical studies prove lansoprazole effectively treats frequent heartburn

In three clinical studies, lansoprazole was shown to be significantly better than placebo in treating frequent heartburn.

How Lansoprazole delayed release orally disintegrating tablets is Sold

This medicine is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About Lansoprazole delayed release orally disintegrating tablets

Call 1-800-719-9260 weekdays 7:30 AM to 5:00 PM EST

Made in Israel

Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Reference ID: 4188168