

TOPCARE LANSOPRAZOLE- lansoprazole tablet, orally disintegrating, delayed release

Topco Associates LLC

Topco Associates LLC. Lansoprazole Drug Facts

Active ingredient (in each tablet)

Lansoprazole 15 mg

Purpose

Acid Reducer

Use

- 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 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 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 care 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
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

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, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

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, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

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

Consumer Information

Treats Frequent Heartburn

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

acid reducer

- May take 1 to 4 days for full effect

Please read the entire package insert before taking

Lansoprazole Delayed Release Orally Disintegrating Tablets.

Save for future reference.

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 tablet 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
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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 care 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 that 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

:8U17400J3

Package/Label Principal Display Panel

TopCare® health

COMPARE TO PREVACID® 24 HR

ACTIVE INGREDIENT

MELTech™

Melts In Your Mouth

MELTS IN YOUR MOUTH • DISSOLVES WITHOUT WATER

Lansoprazole

DELAYED RELEASE ORALLY DISINTEGRATING TABLETS 15 mg

ACID REDUCER

TREATS FREQUENT HEARTBURN

24 HOUR

- May take 1 to 4 days for full effect

STRAWBERRY FLAVOR

14 TABLETS

ONE 14-DAY COURSE OF TREATMENT

actual size



*This product is not manufactured or distributed by Takeda Pharmaceuticals U.S.A., Inc., owner of the registered trademark Prevacid®.

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

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

NDC 36800-295-74

+TopCare®
health

COMPARE TO PREVACID® 24 HR
ACTIVE INGREDIENT*

MELTech™
Melts In Your Mouth

MELTS IN YOUR MOUTH • DISSOLVES WITHOUT WATER

Lansoprazole

DELAYED RELEASE ORALLY DISINTEGRATING
TABLETS 15 mg **ACID REDUCER**

TREATS FREQUENT HEARTBURN



• May take 1 to 4 days
for full effect

**STRAWBERRY
FLAVOR**



14 TABLETS

ONE 14-DAY COURSE
OF TREATMENT

actual
size



8U174 88 C2

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Drug Facts (continued)

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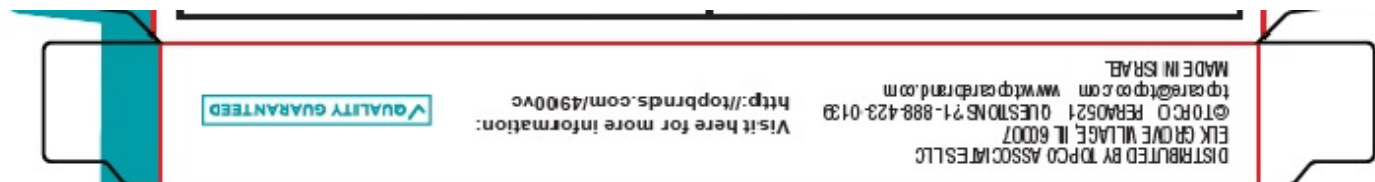
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Inactive ingredients

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



TOPCARE LANSOPRAZOLE			
lansoprazole tablet, orally disintegrating, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-295
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)		LANSOPRAZOLE	15 mg
Inactive Ingredients			
Ingredient Name			Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
COPOVIDONE K25-31 (UNII: D9C330MD8B)			
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MALTITOL (UNII: D65DG142WK)			
MANNITOL (UNII: 3OWL53L36A)			
MEGLUMINE (UNII: 6HG8UB2MUY)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			
Product Characteristics			
Color	WHITE (off white mottled)	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-295-74	14 in 1 CARTON	06/18/2020	
1		1 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	NDA208025	06/18/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 5/2023

Topco Associates LLC