

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.
- lansoprazole 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

- liver disease
- 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 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 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 humidity
- protect product from moisture
- take the tablet immediately after opening individual blister. Do not store the tablet outside the blister pack for future use.

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

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 HR

STRAWBERRY FLAVOR

DISSOLVE TABS

actual size

14 TABLETS

ONE 14-DAY COURSE OF TREATMENT • MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

0 36800 46830 6

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

KEEP THE CARTON. IT CONTAINS 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[®]
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ONE 14-DAY COURSE OF TREATMENT • MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

8U174 88 C3

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose</p> <p>Lansoprazole 15 mg.....Acid Reducer</p>	
<p>Use ■ treats frequent heartburn (occurs 2 or more days a week)</p> <p>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p>	
<p>Warnings</p> <p>Allergy alert:</p> <p>■ do not use if you are allergic to lansoprazole.</p> <p>■ lansoprazole may cause severe skin reactions. Symptoms may include:</p> <p>■ skin reddening ■ blisters ■ rash</p> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use if you have:</p> <p>■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools</p> <p>■ heartburn with lightheadedness, sweating or dizziness</p> <p>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</p> <p>■ 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 ■ liver disease</p> <p>■ had heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>■ frequent wheezing, particularly with heartburn</p> <p>■ 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>■ you need to take this product for more than 14 days</p> <p>■ you need to take more than 1 course of treatment every 4 months</p> <p>■ you get diarrhea ■ you develop a rash or joint pain</p> <p>If pregnant or breast-feeding, ask a health care professional before use.</p> <p>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>Drug Facts (continued)</p> <p>Directions ■ adults 18 years of age and older</p> <p>■ this product is to be used once a day (every 24 hours), every day for 14 days</p> <p>■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>■ take 1 tablet before eating in the morning</p> <p>■ do not crush or chew tablets</p> <p>■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.</p> <p>■ take every day for 14 days ■ do not take more than 1 tablet a day</p> <p>■ do not use for more than 14 days unless directed by your doctor</p> <p>■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (if needed)</p> <p>■ you may repeat a 14-day course every 4 months</p> <p>■ 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</p> <p>■ keep the carton. It contains important information.</p> <p>■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity</p> <p>■ protect product from moisture</p> <p>■ take the tablet immediately after opening individual blister. Do not store the tablet outside the blister pack for future use.</p> <p>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</p> <p>Questions or comments? 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST</p>	

QUALITY GUARANTEED

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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.

■ Patse the head of your bed.

■ Wear loose-fitting clothing around your stomach.

■ If you are overweight, lose weight. ■ If you smoke, quit smoking.

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, UNSPECIFIED (UNII: 2S7830E561)	

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)