

LANSOPRAZOLE- lansoprazole capsule, delayed release
Chain Drug Consortium, LLC

Lansoprazole Delayed-Release Capsules, USP

Drug Facts

Active ingredient (in each capsule)

Lansoprazole USP, 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

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medication)

Stop use and ask 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 at 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

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules
- do not use for more than 14 days unless directed by your doctor

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

Inactive ingredients

acetone, D&C Red #28, D&C Yellow #10, FD&C Blue #1, gelatin, hypromellose, isopropyl alcohol, light magnesium carbonate, methacrylic acid copolymer type C, polyethylene glycol 4000, polysorbate 80, sugar spheres (which contain sucrose and starch), talc, titanium dioxide. Printing Ink contains butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution, titanium dioxide

Questions?

1-888-838-2872 between 9 am and 5 pm ET, Monday – Friday.

Principal Display Panel

Premier Value®

COMPARE TO THE ACTIVE INGREDIENT IN PREVACID® 24 HR*

Treats Frequent Heartburn

**Lansoprazole
Delayed-Release Capsules USP, 15 mg
Acid Reducer**

- May take 1 to 4 days for full effect
- Sodium Free

Does not contain an ingredient derived from wheat, barley or rye

24 HOUR

**Three 14-Day Courses of Treatment
42 Capsules**



LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-756
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
ACETONE (UNII: 1364PS73AF)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (5 MPAS) (UNII: R75537T0T4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	GREEN, PINK	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	L24HR
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-756-14	1 in 1 CARTON	01/23/2017	07/31/2019
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68016-756-42	3 in 1 CARTON	01/23/2017	03/31/2021
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203306	01/23/2017	03/31/2021

