GOOD SENSE LANSOPRAZOLE- lansoprazole capsule, delayed release L. Perrigo Company

Perrigo Lansoprazole Drug Facts

Active ingredient (in each capsule)

Lansoprazole 15 mg

Purpose

Acid Reducer

Use

- treats frequent heartburn (occurs <u>2 or more</u> 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

- 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 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
- close cap tightly after use

Inactive ingredients

D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, hypromellose, low substituted hydroxypropyl cellulose, mannitol, meglumine, methacrylic acid copolymer, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

GOODSENSE® Treats Frequent Heartburn Lansoprazole Delayed-Release Capsules 15 mg Actual Size Acid Reducer 24HR • May take 1 to 4 days for full effect • Sodium Free 14 Capsules One 14-Day Course of Treatment

Compare to active ingredient of Prevacid[®] 24HR





GOOD SENSE LANS					
ansoprazole capsule, delay	yed release				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So		NDC:011	3.111/
		item code (St	Juice	NDC.011	5-1114
Route of Administration	ORAL				
Active Ingredient/Activ	e Moiety				
Ing	gredient Name		Basis of St	trength	Strength
LANSOPRAZOLE (UNII: 0K5C5T	2QPG) (LANSOPRAZOLE - U	INII:0K5C5T2QPG)	LANSOPRAZOL	_E	15 mg
Inactive Ingredients					
-	Ingredient Na	me			Strength
D&C RED NO. 28 (UNII: 767IPO)	2 Y5NH)				
D&C YELLOW NO. 10 (UNII: 35	SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47	7K3TBD)				
FD&C RED NO. 40 (UNII: WZ B9	127XOA)				
GELATIN, UNSPECIFIED (UNII:	2G86QN327L)				
HYPROMELLOSE, UNSPECIFIE	D (UNII: 3NXW29V3WO)				
LOW-SUBSTITUTED HYDROX	PROPYL CELLULOSE, U	NSPECIFIED (UNII: 2	165RE0K14)		
MANNITOL (UNII: 30WL53L36A)					
MEGLUMINE (UNII: 6HG8UB2ML	JY)				
METHACRYLIC ACID - ETHYL	ACRYLATE COPOLYMER	(1:1) TYPE A (UNII: M	NX76LV5T8J)		
POLYETHYLENE GLYCOL, UNS	SPECIFIED (UNII: 3WJQ0SD	W1A)			
POLYSORBATE 80 (UNII: 60ZP	39ZG8H)				
SODIUM LAURYL SULFATE (UN	NII: 368GB5141J)				
TALC (UNII: 7SEV7J4R1U)					
TITANIUM DIOXIDE (UNII: 15FI)	(9V2JP)				
Product Characteristic	S				
Color PINK	, GREEN	Score		no score	

Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	24HR
Contains			

Pa	ackaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0113-1114- 01	1 in 1 CARTON	11/22/2021		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0113-1114- 02	2 in 1 CARTON	11/22/2021		
2		14 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:0113-1114- 03	3 in 1 CARTON	11/22/2021		
3		14 in 1 BOTTLE; Type 0: Not a Combination Product			
Μ	larketing I	nformation			
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ΔN	DA	ANDA202319	11/22/2021		

Labeler - L. Perrigo Company (006013346)

Revised: 5/2023

L. Perrigo Company