

**SUNMARK LANSOPRAZOLE- lansoprazole capsule, delayed release**  
**Strategic Sourcing Services LLC**

-----  
**McKesson Lansoprazole Drug Facts**

**Active ingredient (in each capsule)**

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**

- 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**

sunmark®

COMPARE TO PREVACID® 24 HR ACTIVE INGREDIENT

lansoprazole

Delayed Release Capsules, 15 mg

Acid Reducer

May take 1 to 4 days for full effect

Sodium Free

Treats Frequent Heartburn

24 HOUR

ACTUAL SIZE

14 CAPSULES

GLUTEN FREE

One 14-Day Course of Treatment



## SUNMARK LANSOPRAZOLE

lansoprazole capsule, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0124
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
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUJ)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWL1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

<b>Product Characteristics</b>			
<b>Color</b>	PINK, GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	24HR
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0124-1	1 in 1 CARTON	12/13/2021	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-0124-3	3 in 1 CARTON	12/13/2021	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202319	12/13/2021	

**Labeler** - Strategic Sourcing Services LLC (116956644)