

**LANSOPRAZOLE - lansoprazole capsule, delayed release**  
**Rising Pharma Holdings, Inc.**

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**Lansoprazole Delayed-Release Capsules USP, 15mg**  
**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 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, warnings and package insert before use
- keep the package 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
- close cap tightly after use

**Inactive ingredients**

acetone, D&C Red No. 28, D&C Yellow No. 10, FD&C Blue No. 1, gelatin, hypromellose, isopropyl alcohol, light magnesium carbonate, methacrylic acid copolymer type C, polyethylene glycol, polysorbate 80, sugar spheres (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 or comments? 1-844-874-7464**

## **PATIENT INFORMATION**

### **Treats Frequent Heartburn**

#### **Lansoprazole (lan-SO-pruh-zole)**

#### **Delayed-Release Capsules USP,**

#### **15 mg / Acid Reducer**

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

**Please read the entire package insert before taking Lansoprazole Delayed-Release Capsules, USP Save for future reference.**

### **How Lansoprazole Delayed-Release Capsules, USP Treat Your Frequent Heartburn**

Lansoprazole delayed-release capsules, USP stop acid production at the source - the **pumps** that release acid into the stomach. Lansoprazole delayed-release capsules, USP are taken once a day (every 24 hours), every day for 14 days.

### **What You Can Expect When Taking Lansoprazole Delayed-Release Capsules, USP**

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take lansoprazole delayed-release capsules, USP in the morning before eating. Lansoprazole delayed-release capsules, USP are 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 capsules, USP every day for 14 days to treat your frequent heartburn.

### **Who Should Take Lansoprazole Delayed-Release Capsules, USP**

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 Capsules, USP**

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

### **How to Take Lansoprazole Delayed-Release Capsules, USP**

#### **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.

**When to Take Lansoprazole Delayed-Release Capsules, USP 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
- 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 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 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.

#### **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 Lansoprazole Delayed-Release Capsules, USP effectively treats frequent heartburn**

In three clinical studies, lansoprazole delayed-release capsules, USP were shown to be significantly better than placebo in treating frequent heartburn.

**How Lansoprazole Delayed-Release Capsules, USP are Sold**

Lansoprazole delayed-release capsules, USP are available in 14 capsules, 28 capsules and 42 capsule 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 Capsules, USP**

Call 1-844-474-7464

**Manufactured by:**

Natco Pharma Limited  
Kothur - 509 228, India

**Distributed by:**

Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816

Revised: 11/2020

**PRINCIPAL DISPLAY PANEL**

**Rising®  
742-42**

**NDC -16571-**

**Compare to the active ingredient  
in Prevacid® 24 HR\***

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

**Acid Reducer  
24 Hour  
Treats Frequent Heartburn**

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

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

**Three 14-day Course OF Treatment**

**42 Capsules**



**NDC -16571-742-42**  
Compare to the active ingredient  
in Prevacid® 24 HR\*

# Lansoprazole

## Delayed-Release Capsules USP, 15 mg

**Acid reducer 24 Hour**

**Treats Frequent Heartburn**

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

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

**Three 14-day Courses Of Treatment**     **42 Capsules**

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

**TAMPER-EVIDENT BOTTLE.**

DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BULBON-CRAY BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

**3 BOTTLES INSIDE**

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

**Acid reducer 24 Hour**

**Treats Frequent Heartburn**

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**42 Capsules**

Three 14-day Courses Of Treatment

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**Drug Facts (continued)**

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**Drug Facts (continued)**

**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, polyorbate 80, sugar spheres (which contain sorbitol 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 or comments? 1-844-474-7464**

\* This product is not affiliated with, manufactured by or produced by the holder or owners of Prevacid 24 HR. See 11/2020

Manufactured by: Rising Health Holdings, Inc. 11/2020

Manufactured by: Natco Pharma Limited, Natco - 289 228, India. Sold in: Switzerland, EU, GB, US



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# LANSOPRAZOLE

lansoprazole capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16571-742
<b>Route of Administration</b>	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: 7671P0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B710)	
AMMONIA (UNII: 5138Q19F1X)	

## Product Characteristics

<b>Color</b>	PINK, GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-742-42	3 in 1 CARTON	05/28/2021	
1		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	05/28/2021	

**Labeler** - Rising Pharma Holdings, Inc. (835513529)

## Establishment

Name	Address	ID/FEI	Business Operations
Natco Pharma Limited		918588174	MANUFACTURE(16571-742)

Revised: 5/2021

Rising Pharma Holdings, Inc.