LANSOPRAZOLE- lansoprazole capsule, delayed release
Bryant Ranch Prepack

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

HOW SUPPLIED

NDC: 71335-9694-1: 30 Capsules in a BOTTLE

NDC: 71335-9694-2: 15 Capsules in a BOTTLE

NDC: 71335-9694-3: 60 Capsules in a BOTTLE

NDC: 71335-9694-4: 90 Capsules in a BOTTLE

NDC: 71335-9694-5: 28 Capsules in a BOTTLE

Lansoprazole DR 15mg Capsule (OTC)

GTIN 00371335969417
Lot 208820
Exp 6/22/2025
SN 0123456789

Each delayed-release capsule contains:
Lansoprazole, USP 15 mg

Dispense in a tight, light-resistant container. Keep tightly closed.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see USP controlled Room Temperature).

Keep this and all drugs out of the reach of children.

NDC 71335-**9694**-1

Lansoprazole Delayed-Release Capsules, USP

15 mg

30 Capsules

BRP PHARMACEUTICALS

Repackaged by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Natco Pharma Limited

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-9694(NDC:16571-742)
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, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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	PINK, GREEN	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-9694-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2023	
2	NDC:71335-9694-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2023	
3	NDC:71335-9694-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2023	
4	NDC:71335-9694-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2023	
5	NDC:71335-9694-5	28 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203306	05/28/2021	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9694) , RELABEL(71335-9694)