

**LANSOPRAZOLE- lansoprazole capsule, delayed release
LEADER/ Cardinal Health 110, Inc.**

Lansoprazole Delayed Release Capsules USP

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 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 healthcare 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 days
- 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 – 25°C (68° – 77° F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

Inactive ingredients

FD&C Blue No. 2, gelatin, hydroxypropyl cellulose, iron oxide black, iron oxide red, iron oxide yellow, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate 80, sodium lauryl sulphate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

call **1-888-375-3784**

Consumer Information

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

- Treats Frequent Heartburn
- May take 1 to 4 days for full effect

Please read the entire package insert before taking Lansoprazole Delayed-Release Capsules USP, 15 mg. Save for future reference.

How Lansoprazole Delayed-Release Capsules USP, 15 mg Treat Your Frequent Heartburn

Lansoprazole Delayed-Release Capsules USP, 15 mg stops acid production at the source - the pumps that release acid into the stomach. Lansoprazole Delayed-Release Capsules USP, 15 mg is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking Lansoprazole Delayed-Release Capsules USP, 15 mg

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole Delayed-Release Capsules USP, 15 mg in the morning before eating. Lansoprazole Delayed-Release Capsules USP, 15 mg is 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, 15 mg every day for 14 days to treat your frequent heartburn.

Who Should Take Lansoprazole Delayed-Release Capsules USP, 15 mg

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, 15 mg

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, 15 mg

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, 15 mg 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
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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)

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, 15 mg effectively treat frequent heartburn

In three clinical studies, Lansoprazole Delayed-Release Capsules USP, 15 mg was shown to be significantly better than placebo in treating frequent heartburn.

How Lansoprazole Delayed-Release Capsules USP, 15 mg is Sold

Lansoprazole Delayed-Release Capsules USP, 15 mg are available in 14 capsule, 28 capsule 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, 15 mg

Call 1-888-375-3784

Manufactured by:

Dr. Reddy's Laboratories Limited

Bachupally - 500 090 INDIA

Principal Display Panel

Container : 14's count

LOT
EXP

552280051

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TAMPER EVIDENT: Do not use if seal is broken or missing. Do not use if seal is broken or missing. Do not use if seal is broken or missing.

LEADER[®]

NDC 70000-0069-1

24 Hour
Lansoprazole
Delayed-Release Capsules
USP, 15 mg
Acid Reducer

Treats Frequent Heartburn
May Take 1 to 4 Days for Full Effect

14 CAPSULES
One 14-Day Course of Treatment

IMPORTANT: This label does not contain full product information. See carton for complete information. Read the directions, consumer information leaflet and warnings before use. Retain carton and leaflet for reference.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Made in India

100% Money Back Guarantee
Return to place of purchase if not satisfied.

CIN 5675145 REV. 11/20

PEEL HERE FOR
DIRECTIONS

Research

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

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- 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

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Directions (continued)

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° - 25°C (68° - 77° F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

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).

Questions or comments?

call 1-888-375-3784

Principal Display Panel

Container carton : 14's count



| LANSOPRAZOLE | | | |
|-----------------------------------------------------------------------------|----------------|--------------------|-------------------------------|
| lansoprazole capsule, delayed release | | | |
| | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0069(NDC:55111-739) |
| 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 |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | | |
| GELATIN (UNII: 2G86QN327L) | | | |
| HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW) | | | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | | | |
| Hydroxypropyl Cellulose, Low Substituted (UNII: 2165RE0K14) | | | |
| MAGNESIUM CARBONATE (UNII: 0E53J927NA) | | | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | | | |
| POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE) | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | |

| | |
|-------------------------------------------------|--|
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SUCROSE (UNII: C151H8M554) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|--------------------------------------------------------------------|---------------------|----------|
| Color | PINK (opaque pink colored cap) , GREEN (opaque green colored body) | Score | no score |
| Shape | CAPSULE | Size | 3mm |
| Flavor | | Imprint Code | RDY;398 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70000-0069-1 | 1 in 1 CARTON | 10/30/2020 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0069-2 | 2 in 1 CARTON | 10/30/2020 | |
| 2 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:70000-0069-3 | 3 in 1 CARTON | 10/30/2020 | |
| 3 | | 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 | ANDA202194 | 10/30/2020 | |

Labeler - LEADER/ Cardinal Health 110, Inc. (063997360)

Revised: 11/2023

LEADER/ Cardinal Health 110, Inc.