

TOPCARE LANSOPRAZOLE- lansoprazole capsule, delayed release
Topco Associates LLC

Topco Associates LLC. Lansoprazole Delayed-Release Capsules, 15 mg Acid Reducer 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 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

D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, 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?

1-888-423-0139

Consumer Information

Treats Frequent Heartburn

Lansoprazole

Delayed-Release Capsules 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 15 mg.

Save for future reference.

How Lansoprazole Delayed-Release Capsules 15 mg Treats Your Frequent Heartburn

Lansoprazole Delayed-Release Capsules 15 mg stops acid production at the source – the **pumps** that release acid into the stomach. Lansoprazole Delayed-Release Capsules 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 15 mg

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

Who Should Take Lansoprazole Delayed-Release Capsules 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 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 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 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
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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 15 mg effectively treats frequent heartburn

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

How Lansoprazole Delayed-Release Capsules 15 mg is Sold

Lansoprazole Delayed-Release Capsules 15 mg is 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 15 mg

Call 1-800-719-9260

Distributed By

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: 3T300 00 J6

Package/Label Principal Display Panel

COMPARE TO PREVACID® 24 HR ACTIVE INGREDIENT

Lansoprazole

DELAYED-RELEASE CAPSULES 15 mg ACID REDUCER

OUR PHARMACISTS RECOMMEND

TREATS FREQUENT HEARTBURN

24 HOUR

May take 1 to 4 Days for Full Effect

Sodium Free

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT

actual size

TopCare
health

Lansoprazole

DELAYED-RELEASE CAPSULES 15 mg ACID REDUCER



Scan here for more information.
Call 1-888-423-0139 for more information.

TopCare
health

NDC 36800-117-01

COMPARE TO PREVACID® 24 HR ACTIVE INGREDIENT*

Lansoprazole

DELAYED-RELEASE CAPSULES 15 mg ACID REDUCER

TREATS FREQUENT HEARTBURN



- May take 1 to 4 Days for Full Effect
- Sodium Free

14 CAPSULES • ONE 14-DAY COURSE OF TREATMENT

actual size



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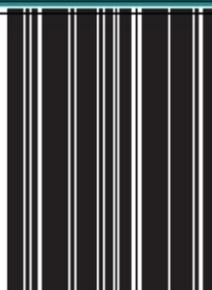


This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Prevacid® 24 HR.



3T3D5 68 C5



1 BOTTLE INSIDE



actual size

Drug Facts

Active ingredient (in each capsule) Purpose
Lansoprazole 15 mg..... Acid Reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
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Ask a doctor before use if you have

- liver disease
- heartburn near 3 months. This may be a sign of a more

Drug Facts (continued)

Stop use and ask a doctor if

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- you need to take more than 1 course of treatment every 4 months
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Directions

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 - 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

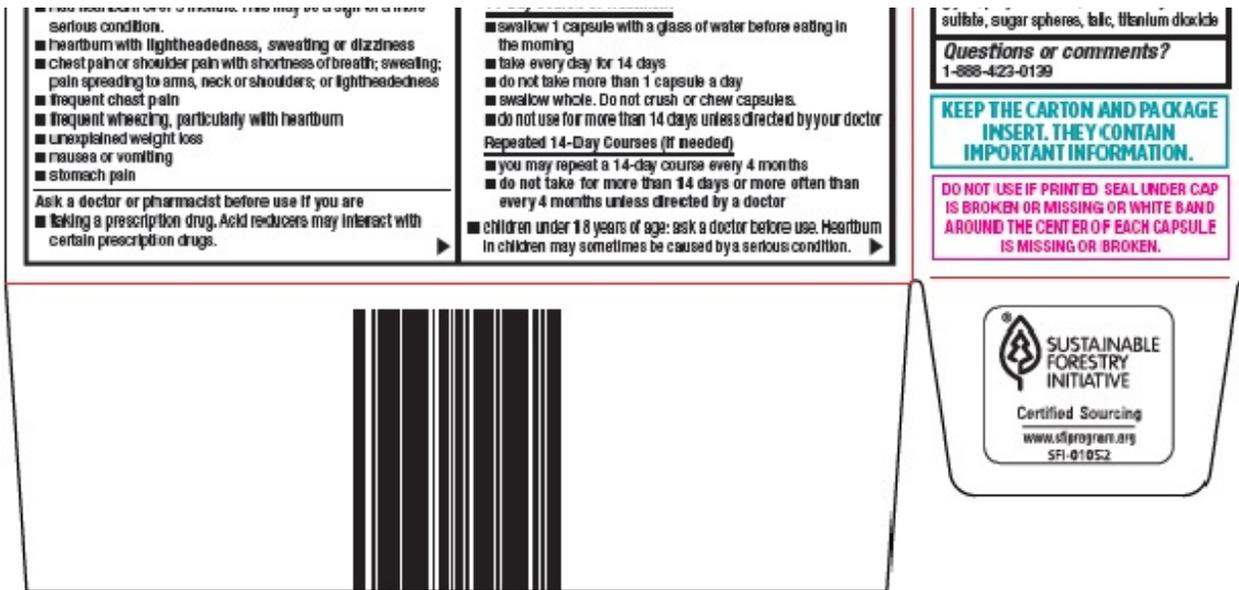
Drug Facts (continued)

Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20-25°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, gelatin, hypromellose, low substituted hydroxypropyl cellulose, mannitol, meglumine, methacrylic acid copolymer, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl



TOPCARE LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-117 |
| 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: 767IP0Y5NH) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| MEGLUMINE (UNII: 6HG8UB2MUY) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------------|---------------------|----------|
| Color | PINK, GREEN | Score | no score |
| Shape | CAPSULE | Size | 16mm |
| Flavor | | Imprint Code | L3T3 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-117-01 | 1 in 1 CARTON | 09/10/2012 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:36800-117-02 | 2 in 1 CARTON | 09/26/2012 | |
| 2 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:36800-117-03 | 3 in 1 CARTON | 09/26/2012 | |
| 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 | ANDA202319 | 09/10/2012 | |

Labeler - Topco Associates LLC (006935977)

Revised: 5/2020

Topco Associates LLC