

**LANSOPRAZOLE- lansoprazole capsule, delayed release  
Cardinal Health (Leader) 70000**

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**DRUG FACTS**

**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

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus or mycophenolate mofetil (immune system medicine)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

**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 (1-800-222-1222) right away.

**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**

black iron oxide, colloidal silicon dioxide, corn starch, FD&C Blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide

**Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## Principal Display Panel

COMPARE TO PREVACID® 24 HR active ingredient†

24 Hour

Lansoprazole

Delayed-Release Capsules USP, 15 mg | Acid Reducer

Sodium-Free

Treats Frequent Heartburn

May Take 1 to 4 Days for Full Effect

Capsules

†This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by GSK Consumer Healthcare, distributor of the Prevacid® 24HR product.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BLACK BAND AROUND THE CENTER OF EACH CAPSULES IS BROKEN OR MISSING.**

**KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

## Package Label

**Drug Facts (continued)**

- Keep product out of high heat and humidity
- Protect product from moisture
- Close cap tightly after use

**Inactive Ingredients**  
black iron oxide, colloidal silicon dioxide, corn starch, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polyacrylate 90, potassium hydroxide, polyurethane glycol, shellac, strong anionic sodium lauryl sulfate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide

**Questions or comments?** Call 1-877-733-2000 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by GSK Consumer Healthcare, distributor of the Prevacid® 24HR product.

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**LEADER™**

**24 Hour**

**Lansoprazole**

Delayed-Release Capsules USP, 15 mg | Acid Reducer

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

**COMPARE TO PREVACID® 24HR**  
active ingredient†

**100% Money Back Guarantee**

**14 CAPSULES**  
One 14-Day Course of Treatment



Actual Size

**1 BOTTLE INSIDE**

**Drug Facts**

Active ingredient (in each capsule)	Purpose
Lansoprazole USP 15 mg	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**

**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**

- Heart disease
- Not 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
- Unexplained weight loss
- Nausea or vomiting
- Stomach pain

**Ask a doctor or pharmacist before use if you are taking**

- warfarin (blood-thinning medicine)
- propranolol (antidotal or anti-psychotic medicines)
- digoxin (heart medicine)
- theophylline (asthma medicine)
- baclofen or mycophenolate mofetil (immune system medicines)
- zalcitabine (medicine for HIV infection)
- methotrexate (arthritis medicine)

**Drug Facts (continued)**

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
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- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor
- Repeat 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**

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CIN 5548342 REV. 8/19



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LEADER Lansoprazole

## LANSOPRAZOLE

lansoprazole capsule, delayed release

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70000-0508

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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

### Product Characteristics

Color	PINK, GREEN	Score	no score
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	MYL;LD15
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0508-3	3 in 1 BOX	07/31/2019	
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0508-1	1 in 1 BOX	07/31/2019	
3		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		

4		Product		
3	NDC:70000-0508-2	2 in 1 BOX	07/31/2019	
3		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203187	07/31/2019	

**Labeler** - Cardinal Health (Leader) 70000 (097537435)

Revised: 8/2019

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