

**LANSOPRAZOLE- lansoprazole capsule, delayed release
Premier Value (Chain Drug Consortium, LLC)**

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

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

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

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.

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. Patients should use the lowest dose and shortest duration of this therapy.**
- 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

Inactive ingredients

colloidal silicon dioxide, D&C red No. 33, D&C yellow No. 10, FD&C blue No. 1, FD&C red No. 40, gelatin, hypromellose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

*COMPARE TO THE ACTIVE INGREDIENT IN PREVACID®24HR

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release Capsules, 15 mg

ACID REDUCER

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

Capsules

Sodium Free

Product of India

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

KEEP OUTER 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 DARK BLUE TO BLACK GELATIN BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

DISTRIBUTED BY: CHAIN DRUG CONSORTIUM, LLC.

3301 NW BOCA RATON BLVD. SUITE 101

BOCA RATON, FL 33431

Product label

<p>Drug Facts</p> <p>Active ingredient (in each capsule) Lansoprazole 15 mg</p> <p>Purpose Acid reducer</p> <p>Use</p> <ul style="list-style-type: none"> • 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 <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to lansoprazole.</p> <p>Do not use</p> <ul style="list-style-type: none"> • 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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • 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, swelling, 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 <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> • warfarin (blood-thinning medicine) • prescription antifungal or anti-yeast medicines • digoxin (heart medicine) • theophylline (asthma medicine) • tacrolimus (immunosuppressant medicine) • zalcitabine (medicine for HIV infection) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • your heartburn continues or worsens 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • adults 18 years of age and older • take every day for 14 days • if you take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • 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 <p>Specialized Use (See Caution, U.S. Insert)</p> <ul style="list-style-type: none"> • 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 <p>Other information</p> <ul style="list-style-type: none"> • Patients should use the lowest dose and shortest duration of this therapy • children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. • 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 	<p>Drug Facts (continued)</p> <p>Inactive ingredients: colloidal silicon dioxide, D&C red No. 35, D&C yellow No. 10, FD&C blue No. 1, FD&C red No. 40, pectin, hydroxypropyl methylcellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polyorbata 80, sucrose, sugar spheres, talc, titanium dioxide</p> <p>Questions or comments? Call 1-877-358-9685 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by Novartis Consumer Health, Inc., distributor of the Prevacid®24HR product.</small></p>	<p style="text-align: right;">NDC 68816-132-00 *COMPARE TO THE ACTIVE INGREDIENT IN PREVACID®24HR</p> <p style="text-align: center;">Premier Value®</p> <p style="text-align: center;">Heartburn Relief 24 Hour™ Lansoprazole Delayed-Release Capsules, 15 mg</p> <p style="text-align: center;">ACID REDUCER</p> <ul style="list-style-type: none"> • May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours • Clinically Proven To Treat Frequent Heartburn <p style="text-align: center;">14 Capsules One 14-Day Course of Treatment</p> <p style="text-align: center;">Sodium Free</p> <p style="text-align: center;">KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.</p> <p style="text-align: center;"><small>DISTRIBUTED BY: CHAIN DRUG CONSORTIUM, LLC. 3301 NW BOCA RATON BLVD, SUITE 101 BOCA RATON, FL 33431</small></p> <p style="text-align: center;"><small>If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.</small></p> <p style="text-align: center;">PLD-C FCC0821 Product of India 1 BOTTLE INSIDE</p> <p style="text-align: center;">Lot No.: Exp. Date:</p> <p style="text-align: right;">8 40986 02843 4</p>
---	---	--	---

Premier Value Heartburn Relief 24 Hour Capsule

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

HUMAN GEN DRUG

NDC 68816

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68016-132(NDC:55648-140)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANSOPRAZOLE (LANSOPRAZOLE)	LANSOPRAZOLE	15 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GELATIN	
HYPROMELLOSES	
MAGNESIUM CARBONATE	
POLYETHYLENE GLYCOLS	
POLYSORBATE 80	
SILICON DIOXIDE	
STARCH, CORN	
SUCROSE	
TALC	
TITANIUM DIOXIDE	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)	

Product Characteristics

Color	PINK, GREEN	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	W140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-132-00	1 in 1 BOX		
1		14 in 1 BOTTLE		
2	NDC:68016-132-01	3 in 1 BOX		
2		14 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202727	07/06/2012	

