

LANSOPRAZOLE- lansoprazole capsule, delayed release
Freds Inc

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

24 Hour Heartburn Relief

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

Sodium Free

Capsules

Compare to the active ingredient in Prevacid®24HR*

*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: fred's, Inc.

4300 New Getwell Rd, Memphis TN 38118

www.fredsinc.com

Product of India

Product label

<p>Drug Facts</p> <p>Active ingredient (in each capsule) Lansoprazole 15 mg</p> <p>Purpose Acid reducer</p> <p>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</p> <p>Warnings Allergy alert: Do not use if you are allergic to lansoprazole.</p> <p>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.</p> <p>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 nighttime, sweating, or dizziness ● chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck, or shoulders, or lightheadedness ● frequent wheezing, particularly with heartburn ● frequent chest pain ● unexplained weight loss ● nausea or vomiting ● stomach pain</p> <p>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) ● sacrochroms (immune system medicine) ● azoformin (medicine for HIV infection)</p> <p>Stop use and ask a doctor if ● your heartburn continues or worsens</p>	<p>Drug Facts (continued)</p> <p>● 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> <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 ● 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</p> <p>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</p> <p>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</p> <p>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.</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients: coloidal silicon dioxide, D&C red No. 33, D&C yellow No. 10, FD&C blue No. 1, FD&C red No. 40, gelatin, hydroxytoluene, magnesium carbonate, methylacrylate copolymer dispersion, polyethylene glycol, polydextrose, sucrose, sugar spheres, talc, titanium dioxide</p> <p>Questions or comments? Call 1-877-753-3665 Monday-Friday 9AM-5PM EST</p>	<p style="text-align: right;">NDC 55315-019-14</p>   <p>24 Hour Heartburn Relief Lansoprazole Delayed-Release Capsules, 15 mg Acid Reducer</p> <p>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> <p>Sodium Free</p> <p>14 Capsules One 14-Day Course of Treatment</p> <p>Compare to the active ingredient in Prevacid®24HR*</p>
<p>KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.</p>			
<p>*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.</p>		<p>DISTRIBUTED BY: fred's, Inc. 4300 NEW GETWELL RD, MEMPHIS, TN 38118 www.fredsinc.com</p>	 <p>0 84579 12619 4</p>
<p>PLD-G FC000866</p>	<p>Product of India</p>	<p>1 BOTTLE INSIDE</p>	<p>Lot No.: Exp. Date:</p>

Fred's 24 Hour Heartburn Relief Capsules

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-019
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. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	

Product Characteristics

Color	PINK, GREEN	Score	no score
Shape	CAPSULE	Size	16 mm
Flavor		Imprint Code	W;140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-019-14	1 in 1 BOX		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202727	12/04/2012	

