

## **LANSOPRAZOLE- lansoprazole capsule, delayed release**

**Freds Inc**

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### **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><b>Drug Facts</b></p> <p><b>Active ingredient (in each capsule)</b> Lansoprazole 15 mg</p> <p><b>Purpose</b> Acid reducer</p> <p><b>Use</b> ● 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><b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to lansoprazole.</p> <p><b>Do not use</b> ● 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><b>Ask a doctor before use if you have</b> ● liver disease ● had heartburn over 3 months. This may be a sign of a more serious condition. ● heartburn with nighttime awakenings, 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 ● trouble or difficulty swallowing ● unexplained weight loss</p> <p><b>Ask a doctor or pharmacist before use if you are taking</b> ● warfarin (blood-thinning medicine) ● prescription antifungal or anti-yeast medicines ● digoxin (heart medicine) ● theophylline (asthma medicine) ● sacrochroms (muscle system medicine) ● azoformin (medicine for HIV infection)</p> <p><b>Stop use and ask a doctor if</b> ● your heartburn continues or worsens</p>	<p><b>Drug Facts (continued)</b></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><b>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 Poison Control Center right away.</b></p> <p><b>Directions</b> ● 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><b>14-Day Course of Treatment</b> ● 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><b>Repeated 14-Day Courses (if needed)</b> ● 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><b>Patients should use the lowest dose and shortest duration of this therapy.</b> ● children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p><b>Other information</b> ● 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><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients:</b> coloidal silicon dioxide, D&amp;C Red No. 33, D&amp;C Yellow No. 10, FD&amp;C Blue No. 1, FD&amp;C Red No. 40, gelatin, hydroxytoluene, magnesium carbonate, methylacrylate copolymer dispersion, polyethylene glycol, polydextrose, sucrose, sugar spheres, talc, titanium dioxide</p> <p><b>Questions or comments?</b> Call 1-877-753-3665 Monday-Friday 9AM-5PM EST</p>	<p style="text-align: right;">NDC 55315-019-14</p>  <p style="text-align: right;">Actual Size</p> <p><b>24 Hour Heartburn Relief</b> Lansoprazole Delayed-Release Capsules, 15 mg</p> <p><b>Acid Reducer</b></p> <p>May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>Clinically Proven To Treat Frequent Heartburn</p> <p><b>Sodium Free</b></p> <p><b>14 Capsules</b> One 14-Day Course of Treatment</p> <p style="text-align: right;">Compare to the active ingredient in Prevacid®24HR*</p>
<p><b>KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.</b></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><b>1 BOTTLE INSIDE</b></p>	<p>Lot No.: Exp. Date:</p>

## Fred's 24 Hour Heartburn Relief Capsules

## LANSOPRAZOLE

lansoprazole capsule, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:55315-019
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LANSOPRAZOLE (LANSOPRAZOLE)	LANSOPRAZOLE	15 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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**

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

**Packaging**

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

**Marketing Information**

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

