

**LANSOPRAZOLE- lansoprazole capsule, delayed release  
Bryant Ranch Prepack**

-----  
**Perrigo Lansoprazole Delayed-Release Capsules, 15 mg 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 or mycophenolate mofetil (immune system medicines)
- 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

### **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

### **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?**

1-800-719-9260

## **Consumer Information**

### ***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

**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
- 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 medicines)
- 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

**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

### Lansoprazole DR 15mg Capsule

<i>Packaged by Bryant Ranch</i>		<i>Barbanc, CA 91504</i>	
<b>Lansoprazole DR 15mg Capsule</b>	LOT	PINK/GREEN CAPSULE L3T3	
	<b>106405</b>		
Compare To:		<b>Store at room temp of 20-25 C (68-77F)</b>	
<b>Prevacid 15mg Capsule</b>		<b>Keep in light resistant container perUSP</b>	
Perrigo New York Inc	Rx Only		
# 30	Exp: MM/YY		
NDC	<b>6362948511</b>	048511106405	

## LANSOPRAZOLE

lansoprazole capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63629-4851(NDC:45802-245)
<b>Route of Administration</b>	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
-----------------	----------

<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>MANNITOL</b> (UNII: 3OWL53L36A)
<b>MEGLUMINE</b> (UNII: 6HG8UB2MUY)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

<b>Product Characteristics</b>			
<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>	L3T3
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-4851-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	
2	NDC:63629-4851-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	
3	NDC:63629-4851-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	
4	NDC:63629-4851-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	
5	NDC:63629-4851-5	28 in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2012	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202319	08/07/2012	

**Labeler** - Bryant Ranch Prepack (171714327)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-4851) , RELABEL(63629-4851)