

**LANSOPRAZOLE- lansoprazole capsule, delayed release**  
**Perrigo New York Inc**

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**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**

### **Package/Label Principal Display Panel**

Compare to Prevacid® 24 HR active ingredient

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

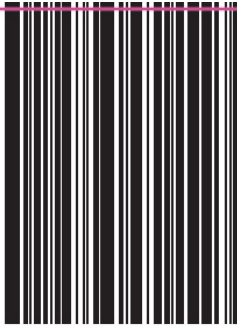
Actual Size

24 HR

Sodium Free

14 Capsules

One 14-Day Course of Treatment



**Perrigo®**

Compare to Prevacid® 24 HR  
active ingredient

NDC 45802-245-01

# Lansoprazole Delayed-Release Capsules, **15 mg**

**Acid Reducer**

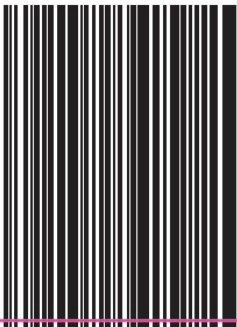
- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

**24 HR** Sodium Free



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

1 Bottle Inside  
ACTUAL SIZE





If your doctor writes a prescription for this product, it may be covered by

- ✓ FSA or HSA Accounts
- ✓ Private Health Plans
- ✓ Medicaid/Medicare

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING OR WHITE BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

**Drug Facts**

**Active ingredient (in each capsule) Purpose**  
Lansoprazole 15 mg.....Acid reducer

**Use**

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**Drug Facts (continued)**

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- methotrexate (arthritis medicine)

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**Drug Facts (continued)**

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**Inactive ingredients**

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**Questions or comments?**

1-800-719-9260



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Distributed By  
**Perrigo®**  
Allegan, MI 49010  
www.perrigo.com



When public and private health plans provide coverage for OTC pharmaceuticals, consumers get relief and drug formularies can reduce costs. At Perrigo, we call it ORx

LOT NO.

EXP.

: 3T3D5 RT C5

**LANSOPRAZOLE**

lansoprazole capsule, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	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	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
D&C RED NO. 28 (UNII: 767IP0Y5NH)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MANNITOL (UNII: 3OWL53L36A)				
MEGLUMINE (UNII: 6HG8UB2MUY)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	PINK, GREEN	Score	no score	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code	L3T3	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-245-01	1 in 1 CARTON		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:45802-245-02	2 in 1 CARTON		
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:45802-245-03	3 in 1 CARTON		
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA202319	08/07/2012		

**Labeler** - Perrigo New York Inc (078846912)