

**LANSOPRAZOLE- lansoprazole capsule, delayed release**  
**Publix Super Markets Inc**

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**Publix Super Markets, Inc. 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 a prescription drug. Acid reducers may interact with certain prescription drugs.

**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
- you develop a rash or joint pain

**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 68-77°F (20-25°C)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

**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

**Consumer Information**

*Treats Frequent Heartburn*

## ***Lansoprazole***

### ***Delayed-Release Capsules 15 mg / Acid Reducer***

- May take 1 to 4 days for full effect
- Sodium Free

**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
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**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
- you develop a rash or joint pain

**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

Distributed By

Perrigo®

Allegan, MI 49010

: 3T300 00 J6

## Package/Label Principal Display Panel

24-HOUR

lansoprazole

DELAYED-RELEASE CAPSULES 15 mg ACID REDUCER

Treats frequent heartburn

May take 1 to 4 days for full effect

Sodium free

Actual Size

42 CAPSULES

THREE-14-DAY COURSES OF TREATMENT

Compare to the active ingredient in Prevacid® 24 HR



**LANSOPRAZOLE**  
 lansoprazole capsule, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-117
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)	LANSOPRAZOLE	15 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	

**Product Characteristics**

<b>Color</b>	PINK, GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	L3T3
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-117-01	1 in 1 CARTON	08/17/2012	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:56062-117-03	3 in 1 CARTON	08/10/2012	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA202319	08/10/2012	

