

**BERKLEY AND JENSEN LANSOPRAZOLE- lansoprazole capsule, delayed release  
BJWC**

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**BJWC 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
- 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 package 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
- 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

## **Questions or comments?**

**1-800-934-1204**

## **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
- 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
- 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 J5

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

Compare to the active ingredient in Prevacid® 24 HR

24 HR

LANSOPRAZOLE DELAYED-RELEASE CAPSULES, 15mg

ACID REDUCER

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

SODIUM FREE

TREATS FREQUENT HEARTBURN

ACTUAL SIZE

THREE 14-DAY COURSES OF TREATMENT

100% MONEY-BACK GUARANTEE

3 BOTTLES – 14 CAPSULES EACH

42 TOTAL CAPSULES

GLUTEN FREE

SODIUM FREE



**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)
- zalcitabine (medicine for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if

- your heartburn continues or worsens
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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).

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.

**QUESTIONS, USE, OR OTHER HELP**

**Questions or comments?**  
1-800-934-1204

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

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

\*This product is not manufactured or distributed by CSK Consumer Healthcare, distributor of Praxid® 24 HR.

# BERKLEY AND JENSEN LANSOPRAZOLE

lansoprazole capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68391-117
<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
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)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4RIU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-117-03	3 in 1 PACKAGE	05/22/2012	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202319	05/22/2012	

**Labeler** - BJWC (159082692)

Revised: 7/2018

BJWC