

**LANSOPRAZOLE- lansoprazole delayed release capsule, delayed release  
Sam's West, Inc.**

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**Lansoprazole DR Capsules USP 15 mg**

**Active ingredient (in each capsule)**

Lansoprazole USP, 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)
- presently taking a prescription drug. Antacids 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 (1-800-222-1222) 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**
- 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**

black iron oxide, colloidal silicon dioxide, corn starch, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide

## **Questions or comments?**

**1-877-446-3679 (1-877-4-INFO-RX).**

## **Consumer Information**

### **Treats Frequent Heartburn**

### **LANSOPRAZOLE DELAYED-RELEASE CAPSULES, USP**

**(lan soe' pra zole)**

**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.**

**Save for future reference.**

### **How Lansoprazole Delayed-Release Capsules Treat Your Frequent Heartburn**

Lansoprazole delayed-release capsules stop acid production at the source – the **pumps** that release acid into the stomach. Lansoprazole delayed-release capsules are taken once a day (every 24 hours), every day for 14 days.

### **What You Can Expect When Taking Lansoprazole Delayed-Release Capsules**

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take lansoprazole delayed-release capsules in the morning before eating. Lansoprazole delayed-release capsules are 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 every day for 14 days to treat your frequent heartburn.

### **Who Should Take Lansoprazole Delayed-Release Capsules**

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**

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 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 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 your 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**
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**Ask a doctor or pharmacist before use if you are taking**

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
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- 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 (1-800-222-1222) right away.

**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 effectively treat frequent heartburn**

In three clinical studies, lansoprazole delayed-release capsules were shown to be significantly better than placebo in treating frequent heartburn.

**How Lansoprazole Delayed-Release Capsules are Sold**

Lansoprazole delayed-release capsules are 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**

**Call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).**

Revised: 4/2018

**PRINCIPAL DISPLAY PANEL**

**Compare to Prevacid® 24HR active ingredient\***

**NDC 68196-030-03**

**Member's Mark™**

**24 hour**

**Lansoprazole Delayed-Release Capsules, USP 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

**Value 3 Pack**

actual size

**42 Capsules**

**Three 14-day courses of treatment**

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

**TAMPER-EVIDENT BOTTLE. DO NOT USE IF TAMPER-EVIDENT INNER OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.**

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

**LABORATORY TESTED - QUALITY ASSURED**

**GLUTEN FREE**

**100% MONEY BACK GUARANTEE**

**QUALITY AND PERFORMANCE**

We would like to hear from you with any comments or suggestions.

In the continental U.S. or Canada, you can call us at 1-877-446-3679 (1-877-4-INFO-RX)  
from 7:30 a.m. to 5 p.m. ET Monday - Friday.

**DISTRIBUTED BY:**

**SAM'S WEST, INC.**

**BENTONVILLE, AR 72716**

## Compare to Prevacid® 24HR active ingredient\*

NDC 68196-030-03

**24 hour**

# Lansoprazole

Delayed-Release  
Capsules, USP  
15 mg  
Acid Reducer

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**42 Capsules**  
Three 14-day courses of treatment

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100% MONEY BACK GUARANTEE

QUALITY AND PERFORMANCE

DO NOT USE IF CAPSULES EXHIBIT ANY OF THE FOLLOWING DEFECTS:

- Capsules that are cracked, broken, or deformed
- Capsules that are discolored or have a different color than the others in the pack
- Capsules that are missing or damaged
- Capsules that are not sealed properly
- Capsules that are not marked with the Member's Mark logo
- Capsules that are not marked with the NDC number
- Capsules that are not marked with the lot number
- Capsules that are not marked with the expiration date
- Capsules that are not marked with the name of the manufacturer
- Capsules that are not marked with the name of the active ingredient
- Capsules that are not marked with the strength of the active ingredient
- Capsules that are not marked with the form of the active ingredient
- Capsules that are not marked with the route of administration
- Capsules that are not marked with the dosage form
- Capsules that are not marked with the number of capsules in the pack
- Capsules that are not marked with the name of the patient
- Capsules that are not marked with the name of the prescriber
- Capsules that are not marked with the name of the pharmacy
- Capsules that are not marked with the name of the hospital
- Capsules that are not marked with the name of the clinic
- Capsules that are not marked with the name of the doctor
- Capsules that are not marked with the name of the nurse
- Capsules that are not marked with the name of the pharmacist
- Capsules that are not marked with the name of the technician
- Capsules that are not marked with the name of the assistant
- Capsules that are not marked with the name of the clerk
- Capsules that are not marked with the name of the receptionist
- Capsules that are not marked with the name of the janitor
- Capsules that are not marked with the name of the security guard
- Capsules that are not marked with the name of the mail carrier
- Capsules that are not marked with the name of the delivery person
- Capsules that are not marked with the name of the courier
- Capsules that are not marked with the name of the driver
- Capsules that are not marked with the name of the pilot
- Capsules that are not marked with the name of the captain
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- Capsules that are not marked with the name of the flight attendant
- Capsules that are not marked with the name of the baggage handler
- Capsules that are not marked with the name of the ground crew
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- Capsules that are not marked with the name of the travel agent
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100% MONEY BACK GUARANTEE

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DP23446 Lansoprazole DR Capsules USP 15 mg

PRINCIPAL DISPLAY PANEL

## Treats Frequent Heartburn

### Lansoprazole Delayed-Release Capsules, USP (lan soe' pra zole) 15 mg Acid Reducer

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

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Save for future reference.

#### How Lansoprazole Delayed-Release Capsules Treat Your Frequent Heartburn

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#### What You Can Expect When Taking Lansoprazole Delayed-Release Capsules

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#### Who Should Take Lansoprazole Delayed-Release Capsules

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

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

##### 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 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

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- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

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In three clinical studies, lansoprazole delayed-release capsules were shown to be significantly better than placebo in treating frequent heartburn.

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#### For Questions or Comments About Lansoprazole Delayed-Release Capsules

Call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).



Manufactured for:  
**Mylan Pharmaceuticals Inc.**  
Morgantown, WV 26505 U.S.A.

Manufactured by:  
**Mylan Laboratories Limited**  
Hyderabad — 500 096, India



# Lansoprazole Insert DP23064

## LANSOPRAZOLE

lansoprazole delayed release capsule, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 196-030
Route of Administration	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
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROUS FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
AMMONIA (UNII: 5138Q19F1X)	

### Product Characteristics

Color	GREEN (green opaque cap; pink opaque body)	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	MYL;LD15
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-030-03	3 in 1 PACKAGE	07/06/2017	
1	NDC:68196-030-01	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		ANDA203187	07/06/2017	

**Labeler** - Sam's West, Inc. (051957769)