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

Lansoprazole Delayed Release Capsules USP

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
- lansoprazole may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools.
- 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**

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.
- 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 healthcare 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 and warnings before use
- keep the carton. It contains 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 28, FD&C Blue No.1, FD&C Green 3, FD&C Red 40, gelatin, hydroxypropyl cellulose, iron oxide black, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate 80, sodium lauryl sulphate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

call **1-888-375-3784**

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.

Distributed by:

Dr. Reddy's Laboratories Inc.,

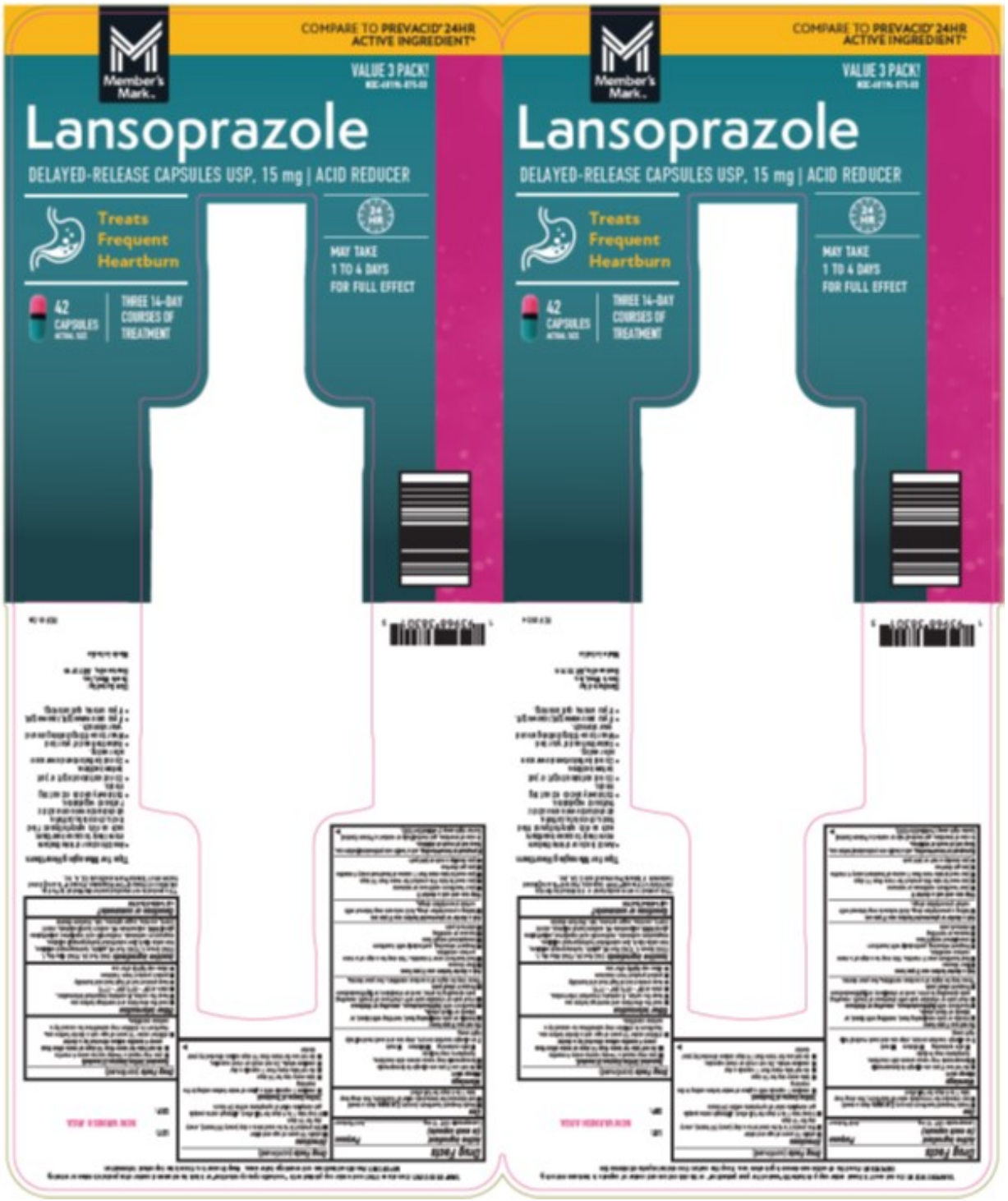
Princeton, NJ 08540

Revised: 01/2023

Principal Display Panel

Container : 14's count

Container carton : 14's count



LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68196-075(NDC:43598-109)
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
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (opaque cyan colored cap) , pink (opaque pink colored body)	**Score**	no score
Shape	CAPSULE	**Size**	3mm
Flavor		**Imprint Code**	RDY;398
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-075-03	3 in 1 PACKAGE	02/29/2024	
1	NDC:68196-075-01	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	ANDA202194	04/12/2022	

Labeler - Sam's West Inc. (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging, LLC		143213275	repack(68196-075) , relabel(68196-075)

Revised: 2/2024

Sam's West Inc.