LANSOPRAZOLE- lansoprazole capsule, delayed release
Safeway, Inc.

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

Clostridium difficile-associated diarrhea (CDAD): A diagnosis of CDAD should be considered for patients taking Proton Pump Inhibitors (PPIs) who develop diarrhea that does not improve. Symptoms include:

- watery stool
- abdominal pain
- fever

Patients should seek immediate care from a healthcare professional if these symptoms do not go away while taking this medication.

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 (immune system medicine)
- atazanavir (medicine for HIV infection)

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

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.

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. Patients should use the lowest dose and shortest duration of this therapy.**

- 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

colloidal silicon dioxide, D&C Red No. 33, D&C Yellow No. 10, FD&C Blue No. 1, FD&C Red No. 40, gelatin, hypromellose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

Call **1-888-SAFEWAY**

Monday-Friday 7AM-6PM PST

Principal Display Panel

Compare to Active Ingredient in Prevacid®24HR*

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

SEE NEW WARNINGS INFORMATION

CAPSULES 14-DAY COURSE OF TREATMENT

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

TAMPER-EVIDENT BOTTLE

Do not use if inner foil seal imprinted with "Sealed For Your Protection" or dark blue to black gelatin band around the center of each capsule is missing or broken.

DISTRIBUTED BY SAFEWAY INC.

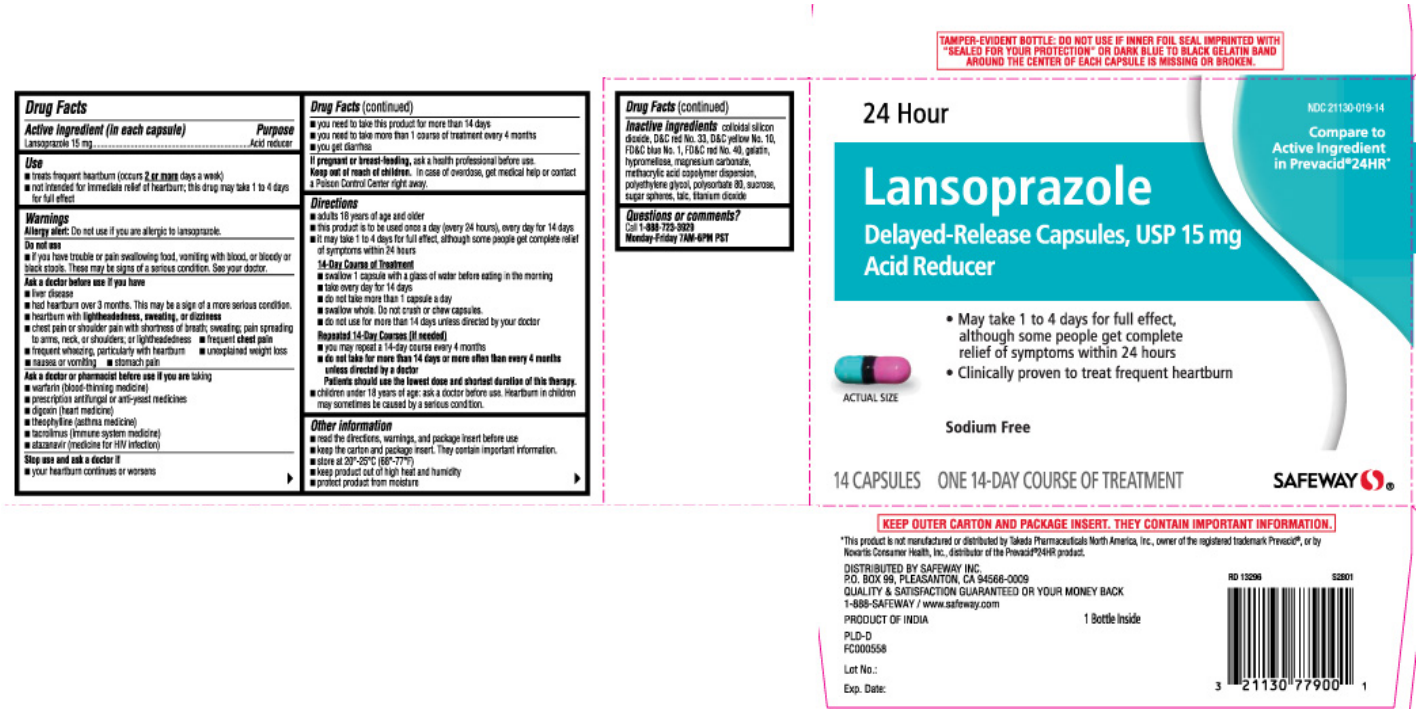
P.O. BOX 99, PLEASANTON, CA 94566-0009

1-888-SAFEWAY / www.safeway.com

Product of India

*This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by Novartis Consumer Health, Inc., distributor of the Prevacid®24HR product.

Product label



Safeway Lansoprazole Capsule

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-019(NDC:64679-140)
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. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
POLYETHYLENE GLYCOLS (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	PINK, GREEN	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	W140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-019-14	1 in 1 BOX		
1		14 in 1 BOTTLE		
2	NDC:21130-019-42	3 in 1 BOX		
2		14 in 1 BOTTLE		
3	NDC:21130-019-28	2 in 1 BOX		
3		14 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202727	12/31/2012	

Labeler - Safeway, Inc. (009137209)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 1/2013 Safeway, Inc.