LANSOPRAZOLE 24 HR- lansoprazole capsule, delayed release
Lannett Company, Inc.

Drug Facts

Active ingredient

Lansoprazole 15mg

Purpose

Acid reducer

Uses

● 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 care 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 Course of Treatment (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 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

ammonium hydroxide, black iron oxide, butyl alcohol, dehydrated alcohol, FD&C Blue #1, FD&C Red #40, gelatin, hypromellose, iron oxide yellow, isopropyl alcohol, magnesium carbonate, mannitol, methacrylic acid and ethyl acrylate copolymer, polyethylene glycol, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, sodium starch glycolate, sugar sphere, talc, titanium dioxide

Questions or Comments

1-844-834-0530

Distributed by:

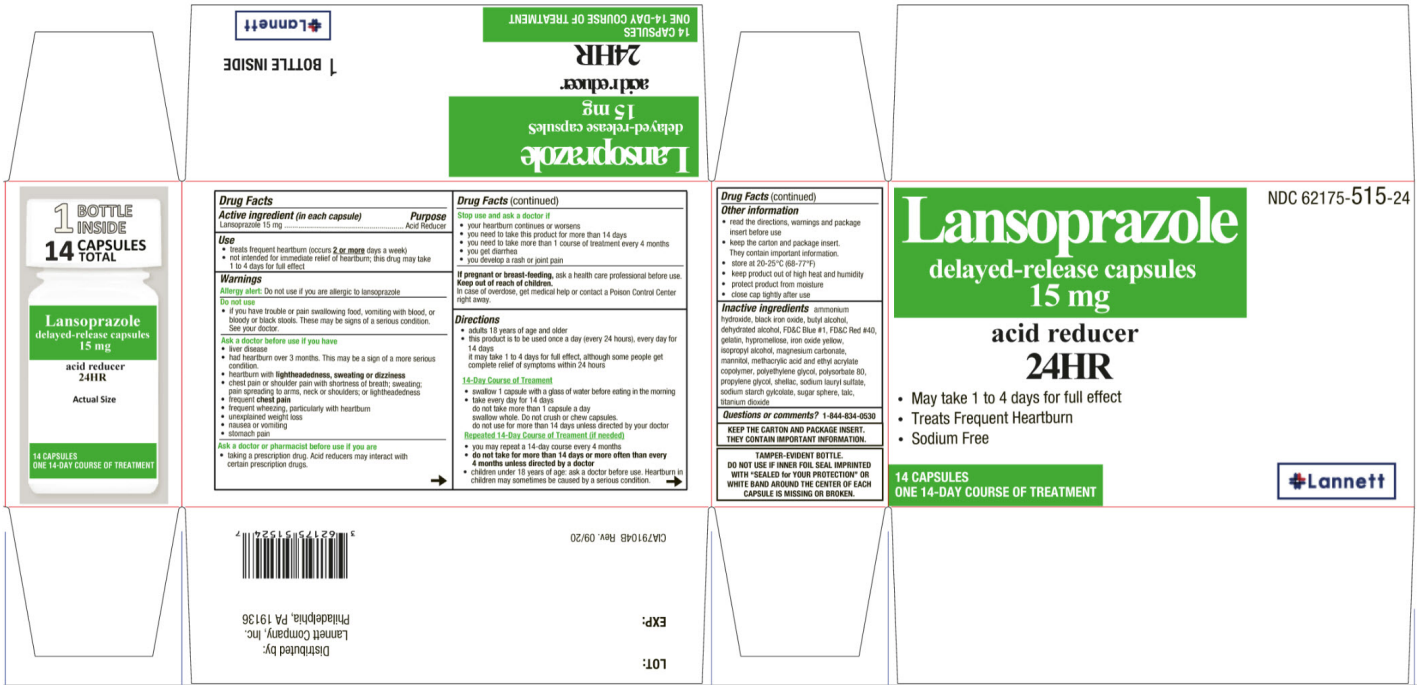
Lannett Company, Inc.

Philadelphia, PA 19136

CIA79102B

Rev. 09/20

Package/Label Principal Display Panel



LANSOPRAZOLE 24 HR

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62175-515
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**
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MANNITOL (UNII: 3OWL53L36A)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN (opaque green cap) , WHITE (opague white body)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	KU;515
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62175-515-24	1 in 1 CARTON	09/29/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62175-515-12	2 in 1 PACKAGE, COMBINATION	09/29/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:62175-515-52	3 in 1 PACKAGE, COMBINATION	09/29/2017	
3		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	ANDA207157	09/29/2017	

Labeler - Lannett Company, Inc. (006422406)

Revised: 9/2020 Lannett Company, Inc.