

**LANSOPRAZOLE- lansoprazole capsule, delayed release**  
**Wal-Mart Stores Inc**

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**Lansoprazole Delayed Release Capsules USP**

**Active ingredient(s)**

Lansoprazole USP, 15 mg

**Purpose**

Acid reducer

**Use(s)**

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

**Stop use and ask 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

**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 days
- 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 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**

FD&C Blue No. 2, gelatin, hydroxypropyl cellulose, iron oxide black, iron oxide red, iron oxide yellow, 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**

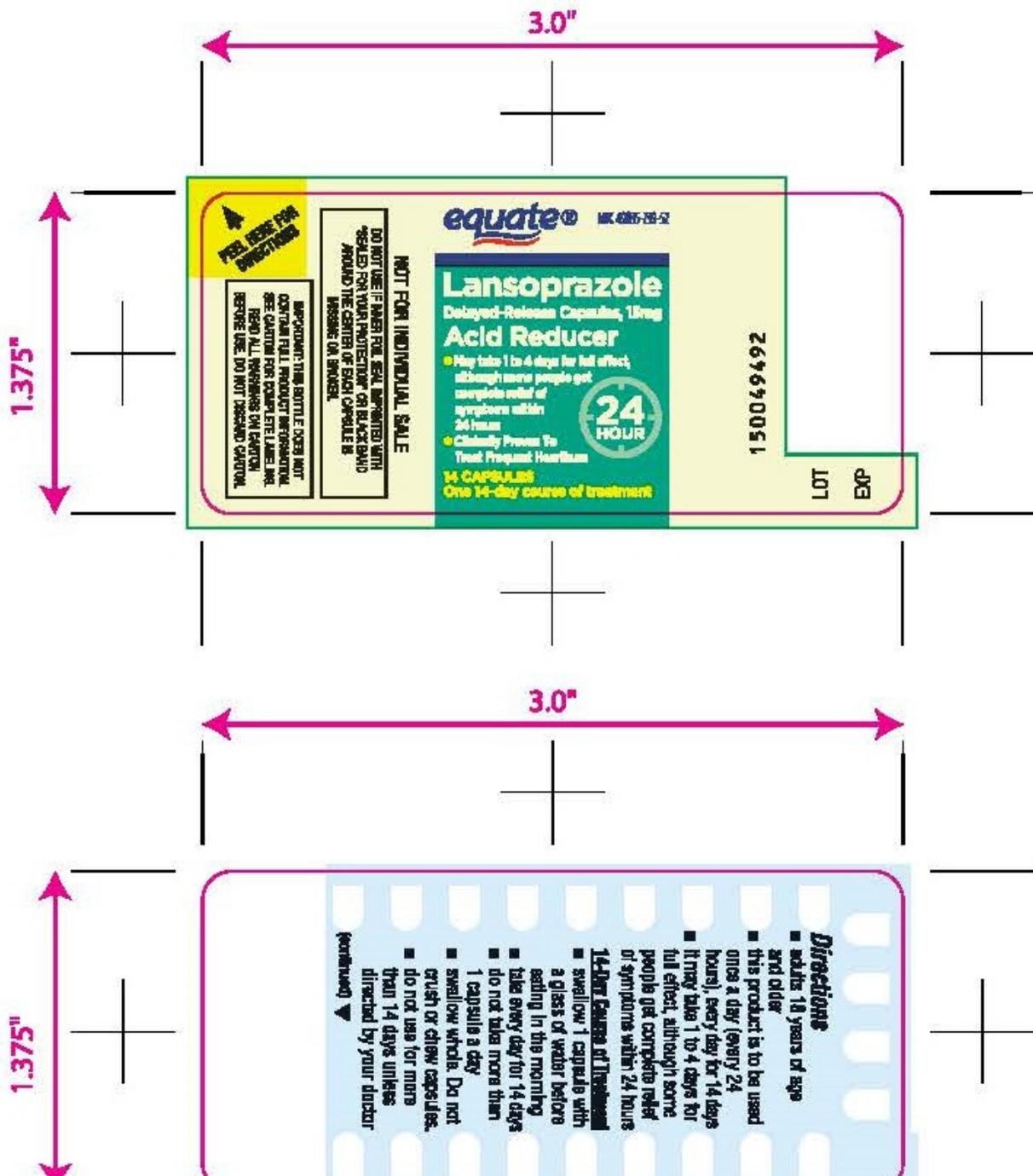
Manufactured by:

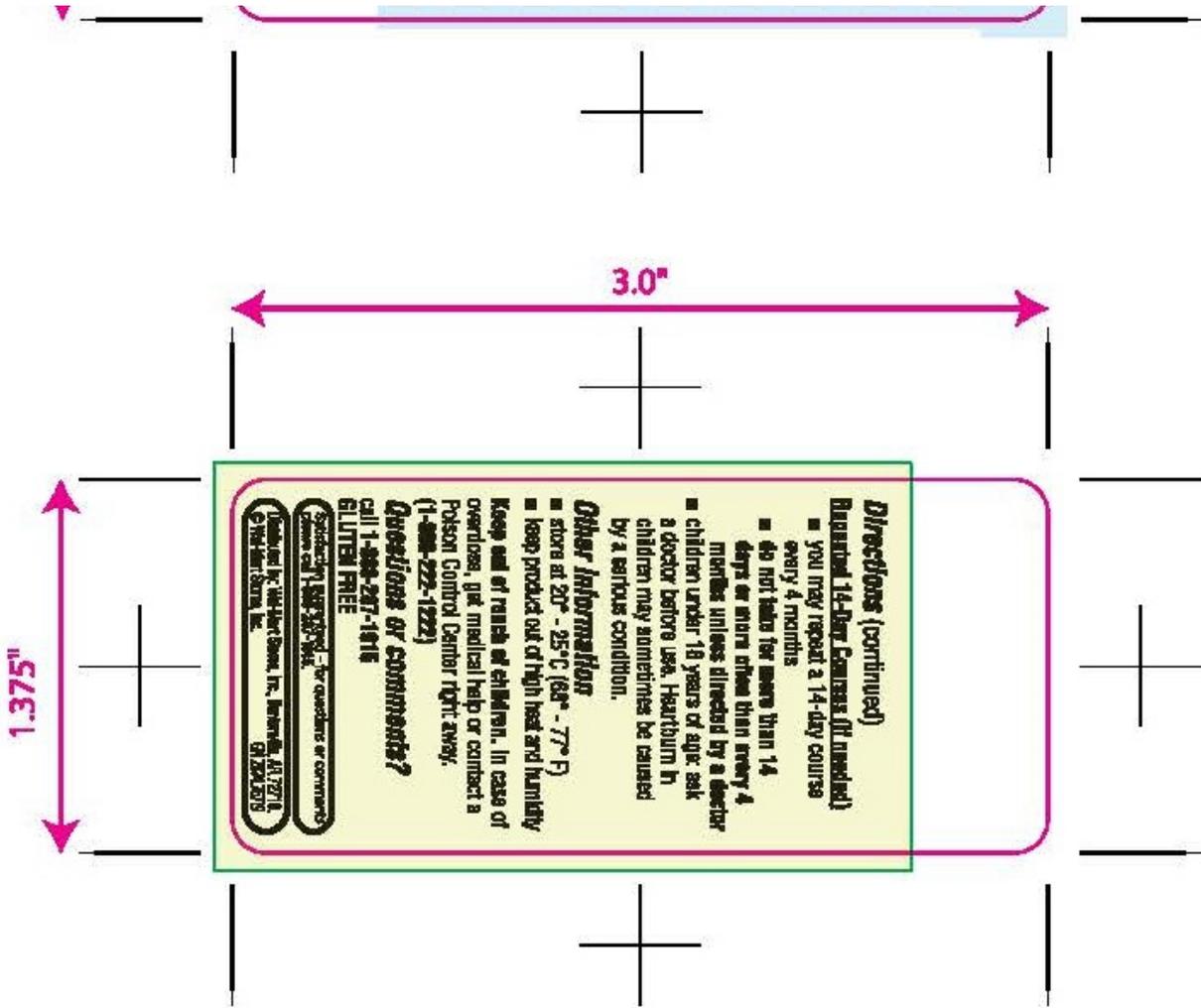
**Dr. Reddy's Laboratories Limited**

Bachupally - 500 090 INDIA

## Principal Display Panel - Container

Container 14's count





**Principal Display Panel**

**Container carton : 14's count**



# LANSOPRAZOLE

lansoprazole capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-739
<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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>HYDROXYPROPYL CELLULOSE</b> (UNII: RFW2ET671P)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED</b> (UNII: 2165RE0K14)
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA)
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	PINK (opaque pink colored cap) , GREEN (opaque green colored body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	3mm
<b>Flavor</b>		<b>Imprint Code</b>	RDY;398
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-739-27	2 in 1 PACKAGE, COMBINATION	05/18/2012	09/01/2014
1	NDC:49035-739-52	14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49035-739-33	3 in 1 PACKAGE, COMBINATION	05/18/2012	09/01/2014
2	NDC:49035-739-52	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	05/18/2012	

**Labeler** - Wal-Mart Stores Inc (051957769)

### Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (FTO III)		918608162	analysis(49035-739) , manufacture(49035-739)

