LANSOPRAZOLE- lansoprazole capsule, delayed release
Wockhardt USA LLC.

Lansoprazole Delayed-Release Capsules USP, 15 mg

OTC - ACTIVE INGREDIENT SECTION

Lansoprazole 15 mg

OTC - PURPOSE SECTION

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 (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.

OTC - 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**
- 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 INGREDIENT

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

OTC - QUESTIONS

Call **1-800-346-6854**

Poison Control Center:

Call **1-800-222-1222**

Manufactured by:

Wockhardt Limited

Mumbai, India.

Distributed by:

Wockhardt USA LLC.

20 Waterview Blvd.

Parsippany, NJ 07054

USA.

Iss.130212

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

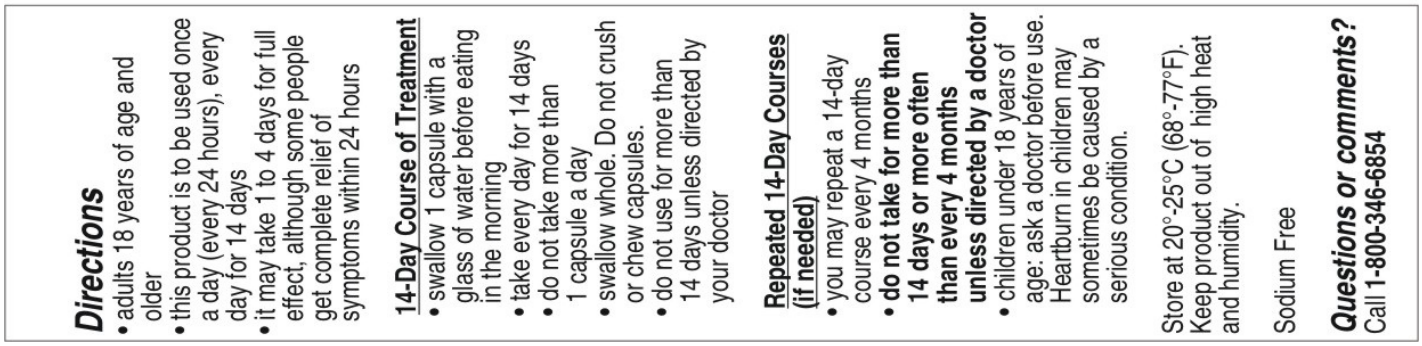
NDC 64679-140-01

15 mg

14 C pack

Front Panel

Back Panel



LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	

Product Characteristics

Color	PINK (Opaque dark pink cap) , GREEN (Opaque dark green body)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	W;140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-140-00	4500 in 1 POUCH; Type 0: Not a Combination Product	05/18/2012	
2	NDC:64679-140-01	1 in 1 CARTON	05/18/2012	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:64679-140-08	2 in 1 CARTON	05/18/2012	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:64679-140-09	3 in 1 CARTON	05/18/2012	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:64679-140-07	1 in 1 CARTON	05/18/2012	
5		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:64679-140-10	2 in 1 CARTON	05/18/2012	
6		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:64679-140-11	3 in 1 CARTON	05/18/2012	
7		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202727	05/18/2012	

Labeler - Wockhardt USA LLC. (170508365)

Registrant - Wockhardt USA LLC. (170508365)

Establishment

Name	Address	ID/FEI	Business Operations
Wockhardt Limited		916489953	ANALYSIS(64679-140) , LABEL(64679-140) , MANUFACTURE(64679-140) , PACK(64679-140)

Revised: 11/2019 Wockhardt USA LLC.