LANSOPRAZOLE- lansoprazole capsule, delayed release Wockhardt Limited

Lansoprazole Delayed-Release Capsules USP, 15 mg

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

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
- 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 1-800-346-6854

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

adults 18 years of age and

Directions

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Front Panel



Back Panel

unless directed by a doctor Questions or comments? Call 1-800-346-6854 this product is to be used once 14-Day Course of Treatment 1 capsule a day
 swallow whole. Do not crush age: ask a doctor before use. glass of water before eating it may take 1 to 4 days for full a day (every 24 hours), every effect, although some people sometimes be caused by a in the morning • take every day for 14 days do not take for more than 14 days unless directed by Repeated 14-Day Courses Keep product out of high heal children under 18 years of swallow 1 capsule with a Heartburn in children may Store at 20°-25°C (68°-77°F). symptoms within 24 hours do not use for more than vou may repeat a 14-day 14 days or more often course every 4 months do not take more than than every 4 months get complete relief of or chew capsules. serious condition. day for 14 days your doctor (if needed) Sodium Free and humidity

BOTTLE INSIDE

TEMPER-EVIDENT BOTTLE.
DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH
O'SEALED for YOUR PROTECTION" OR DARK BLUE TO
BLACK GELATIN BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

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

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking Active ingredient (in each capsule) Purpose

Drug Facts

Acid reducer Lansoprazole 15 mg

- treats frequent heartburn (occurs 2 or more
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect days a week

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

you need to take this product for more than

your heartburn continues or worsens

Stop use and ask a doctor if

· you need to take more than 1 course of

14 days

treatment every 4 months

 if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools.
 These may be signs of a serious condition. Do not use

Ask a doctor before use if you have

See your doctor.

- liver disease
- · had heartburn over 3 months. This may be a sign of a more serious condition.

 • heartburn with lightheadedness, sweating
 - or dizziness
- breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness chest pain or shoulder pain with shortness of

24 hours), every day for 14 days

it may take 1 to 4 days for full effect, although

this product is to be used once a day (every

adults 18 years of age and older

Directions

some people get complete relief of symptoms

within 24 hours

- frequent chest pain
- frequent wheezing, particularly with heartburn
 unexplained weight loss
 - nausea or vomiting
 - stomach pain



14-Day Course of Treatment
• swallow 1 capsule with a glass of water
before eating in the morning

Drug Facts (continued)

- take every day for 14 days
- swallow whole. Do not crush or chew capsules. do not take more than 1 capsule a day
 - · do not use for more than 14 days unless directed by your doctor

prescription antifungal or anti-yeast medicines

warfarin (blood-thinning medicine)

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

theophylline (asthma medicine)

digoxin (heart medicine)

- 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)

overdose, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. In case of

professional before use.

If pregnant or breast-feeding, ask a health

 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 1-800-346-6854 Poison Control Center: Call 1-800-222-1222

NDC 64679-140-01

Delayed-Release Capsules, USP Lansoprazole

15 mg Acid Reducer

- although some people get complete relief of symptoms within 24 hours May take 1 to 4 days for full effect,
- Clinically Proven To Treat Frequent Heartburn

Sodium Free



CAPSULES
One 14 Day Course of Treatment

1 BOTTLE INSIDE

WOCKHARDT

Wockhardt USA LLC. 20 Waterview Blvd. Manufactured by: Wockhardt Limited, Distributed by: Mumbai, India.

Iss. 130212

LOT: NON WARMSHAREA EXP.

Parsippany, NJ 07054 USA.

BOTTLES INSIDE

IS MISSING OR BROKEN. TEMPER-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 KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

15 mg Acid Reducer

Capsules, USP Delayed-Release Lansoprazole

34679-140-08

2 BOTTLES INSIDE

28 CAPSULES TOTAL

Delayed-Release Capsules, USP Lansoprazole

15 mg Acid Reducer

Actual Size

One 14 Day Course of Treatment

Sodium Free

Drug Facts

Active ingredient (in each capsule) -ansoprazole 15 mg

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

Acid reducer

Purpose

Drug Facts (continued)

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartbum; this drug may take 1 to 4 days for full effect

Namings

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

 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

adults 18 years of age and older

Directions

swallow 1 capsule with a glass of water before eating in the morning

14-Day Course of Treatment relief of symptoms within 24 hours

Keep out of reach of children. In case of overdose, get medical help or

contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional before use. you need to take more than 1 course of treatment every 4 months

you need to take this product for more than 14 days

your heartburn continues or worsens

Stop use and ask a doctor if

- 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)



 children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

do not take for more than 14 days or more often than every 4 months

unless directed by a doctor

 you may repeat a 14-day course every 4 month: Repeated 14-Day Courses (if needed)

do not use for more than 14 days unless directed by your doctor

swallow whole. Do not crush or chew capsules.

do not take more than 1 capsule a day

take every day for 14 days





Drug Facts (continued)

Other information

- · read the directions, warnings and package
- 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

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

Questions or comments?

Poison Control Center: Call 1-800-346-6854

Call 1-800-222-1222



Release Capsules, USF Lansoprazole Delayed-

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



CAPSULES

Iwo 14 Day Courses of Treatment

Manufactured by:

Wockhardt Limited, Mumbai, India.

ss.130212

Distributed by: Wockhardt USA LLC. 20 Waterview Blvd.

Parsippany, NJ 07054 USA.

Actual size: 42

BOT TLES INSIDE

TEMPER-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.

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

15 mg Acid Reducer

Delayed-Release Capsules, USP Lansoprazole

34679-140-09

3 BOTTLES INSIDE

Active ingredient (in each capsule,

Drug Facts

-ansoprazole 15 mg.

42 CAPSULES TOTAL

Delayed-Release Capsules, USP Lansoprazole

15 mg Acid Reducer

Actual Size

Ask a doctor or pharmacist before use if you are taking

prescription antifungal or anti-yeast medicines

digoxin (heart medicine)

warfarin (blood-thinning medicine)

One 14 Day Course of Treatment

Sodium Free

Drug Facts (continued)

Purpose

tacrolimus (immune system medicine)

Acid reducer

atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

your heartburn continues or worsens

not intended for immediate relief of heartburn; this drug may take 1 to 4 days

for full effect

Narnings

Do not use

treats frequent heartburn (occurs 2 or more days a week)

- · you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

Keep out of reach of children. In case of overdose, get medical help or If pregnant or breast-feeding, ask a health professional before use. contact a Poison Control Center right away.

Directions

if you have trouble or pain swallowing food, womiting with blood, or bloody or

Allergy alert: Do not use if you are allergic to lansoprazole

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

chest pain or shoulder pain with shortness of breath; sweating; pain

spreading to arms, neck or shoulders; or lightheadedness

frequent wheezing, particularly with heartburn

· frequent chest pain

unexplained weight loss

nausea or vomiting

stomach pain

heartburn with lightheadedness, sweating or dizziness

- 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

take every day for 14 days

swallow 1 capsule with a glass of water before eating in the morning

- 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 month
- 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.



mm x 11 mm

Drug Facts (continued)

Other information

- read the directions, warnings and package
- 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

Inactive ingredients

protect product from moisture

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

Questions or comments?

Poison Control Center: Call 1-800-346-6854

Call 1-800-222-1222



Release Capsules, USF Lansoprazole Delayed-

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



CAPSULES

Three 14 Day Courses of Treatment

Manufactured by:

Wockhardt Limited, Mumbai, India. ss.130212

Parsippany, NJ 07054 USA. Wockhardt USA LLC. 20 Waterview Blvd. Distributed by:

Actual size: 42

NDC 64679-140-05 YOUR PROTECTION" OR IMPORTANT: THIS BOTTLE DOES NOT CONTAIN FULL PRODUCT INFORMATION SEE CARTON FOR COMPLETE LABELING. READ ALL WARNINGS ON CARTON BEFORE USE DO NOT DISCARD CARTON. Lansoprazole Delayed-Release Capsules, USP 15 mg DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED for Y DARK BLUE TO BLACK GELATIN BAND AROUND THE CENTER MISSING OR BROKEN. 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 THIS BULK CONTAINER IS NOT FOR CONSUMER SALE. NOT FOR HOUSEHOLD USE. Sodium Free WOCKHARDT 1000 **CAPSULES**

Drug Facts
Active ingredient (in each capsule) Purpose
Lansoprazole 15 mg......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

trequent cnest pain • trequent 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 Drug Facts (continued)

for full effect, although some people get complete relief of symptom 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 ma sometimes be caused by a serious condition.

Other information

 read the directions, warnings and package insert before use • keep th 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 1-800-346-6854

Manufactured by: Wockhardt Limited, Mumbai, India.

Distributed by: Wockhardt USA LLC. 20 Waterview Blvd., Parsippany, NJ 07054,

lss.130212

NON VARNISH AREA



LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55648-140

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLANSOPRAZOLE (UNII: 0 K5C5T2QPG) (LANSOPRAZOLE - UNII:0 K5C5T2QPG)LANSOPRAZOLE15 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: 3NXW29 V3WO)		
MAGNESIUM CARBO NATE (UNII: 0 E53J9 27NA)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
SUCROSE (UNII: C151H8M554)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
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	16 mm	
Flavor		Imprint Code	W;140	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55648-140-00	4500 in 1 POUCH		
2	NDC:55648-140-01	1 in 1 CARTON		
2		14 in 1 BOTTLE		
3	NDC:55648-140-08	2 in 1 CARTON		
3		14 in 1 BOTTLE		
4	NDC:55648-140-09	3 in 1 CARTON		
4		14 in 1 BOTTLE		
5	NDC:55648-140-07	1 in 1 CARTON		
5		14 in 1 BLISTER PACK		
6	NDC:55648-140-10	2 in 1 CARTON		
6		14 in 1 BLISTER PACK		
7	NDC:55648-140-11	3 in 1 CARTON		
7		14 in 1 BLISTER PACK		

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

Labeler - Wockhardt Limited (650069115)

Registrant - Wockhardt Limited (650069115)

Establishment				
Name	Address	ID/FEI	Business Operations	
Wockhardt Limited		916489953	Manufacture	

Revised: 5/2012 Wockhardt Limited