

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Front Panel

<p>Manufactured by: Wockhardt Limited, Mumbai, India. Iss.130212</p>	<p>Distributed by: Wockhardt USA LLC., 20 Waterview Blvd., Parsippany, NJ 07054 USA.</p>	<p>LOT: EXP.: L 1004167949</p>	<p>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.</p>	<p style="text-align: right;">NDC 64679-140-01</p> <p>Lansoprazole Delayed-Release Capsules, USP</p> <p>15 mg Acid Reducer</p> <ul style="list-style-type: none"> • 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 <p>14 CAPSULES One 14 Day Course of Treatment</p> 	<p>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.</p>	<p>PEEL CORNER FOR DIRECTIONS</p>
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Back Panel

<p>Directions</p>	<ul style="list-style-type: none"> • 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 	<p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • 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 	<p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> • 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. 	<p>Store at 20°-25°C (68°-77°F). Keep product out of high heat and humidity.</p>	<p>Sodium Free</p>	<p>Questions or comments? Call 1-800-346-6854</p>
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1 BOTTLE INSIDE

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.

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
- unexplained weight loss
- nausea or vomiting
- stomach pain

Drug Facts (continued)

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.

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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
- 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
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- 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

NDC 64679-140-01

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



14

CAPSULES

One 14 Day Course of Treatment



Manufactured by:
Wockhardt Limited,
Mumbai, India.

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

LOT:



EXP:

Iss. 130212

Actual size: 34 mm x 9 mm

34679-140-08

**2 BOTTLES
INSIDE**

**28 CAPSULES
TOTAL**

**Lansoprazole
Delayed-Release
Capsules, USP**

15 mg Acid Reducer

Actual Size

One 14 Day Course of Treatment

Sodium Free



2 BOTTLES INSIDE

**Lansoprazole
Delayed-Release
Capsules, USP**

15 mg Acid Reducer

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
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Drug Facts

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Lansoprazole 15 mg.....Acid reducer

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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)

Drug Facts (continued)

- 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

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- you may repeat a 14-day course every 4 months
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Drug Facts (continued)

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
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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, poly sorbate 80, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

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Poison Control Center :

Call 1-800-222-1222



NDC 6

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



28
CAPSULES

Two 14 Day Courses of Treatment



Manufactured by: Wockhardt Limited, Mumbai, India.
Distributed by: Wockhardt USA LLC, 20 Waterview Blvd, Parsippany, NJ 07054 USA.
Iss.130212

LOT: **NON VARI**
EXP.: **NON VARI**
Actual size: 42

54679-140-09

3 BOTTLES INSIDE
42 CAPSULES TOTAL
Lansoprazole Delayed-Release Capsules, USP
15 mg Acid Reducer

Actual Size
One 14 Day Course of Treatment

Sodium Free

3 BOTTLES INSIDE

15 mg Acid Reducer

Lansoprazole Delayed-Release Capsules, USP

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.

Drug Facts

Active ingredient (in each capsule)

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
- 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)

Drug Facts (continued)

- 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
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- **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.

WISH AREA
2 mm x 11 mm

Drug Facts (continued)

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, poly sorbate 80, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?

Call 1-800-346-6854

Poison Control Center :

Call 1-800-222-1222



NDC 1

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



42
CAPSULES

Three 14 Day Courses of Treatment



Manufactured by: Wockhardt Limited, Mumbai, India.
Distributed by: Wockhardt USA LLC, 20 Waterview Blvd, Parsippany, NJ 07054 USA.
Iss.130212

LOT: ~~NON VARI~~
EXP.: ~~NON VARI~~
Actual size: 42

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.

NDC 64679-140-05

Lansoprazole Delayed-Release Capsules, USP

15 mg

Acid Reducer

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.

- 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

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
• 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 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.

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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, USA.

Iss.130212

LOT: NON VARNISH AREA EXP.: NON VARNISH AREA

Actual size: 34 mm x 9 mm

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 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: 3WJQ0SDW1A)			
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: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