

LANSOPRAZOLE- lansoprazole capsule, delayed release
Rite Aid Corporation

DRUG FACTS

Active ingredient (in each capsule)

Lansoprazole USP, 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 or mycophenolate mofetil (immune system medicine)

- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

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 professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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
- close cap tightly after use

Inactive ingredients

black iron oxide, colloidal silicon dioxide, corn starch, FD&C Blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredient in Prevacid® 24HR*

LANSOPRAZOLE

Delayed-Release Capsules USP, 15 mg

24HR

Acid Reducer

TREATS FREQUENT HEARTBURN

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

CAPSULES

†This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by GSK Consumer Healthcare, distributor of the Prevacid® 24HR product.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BLACK BAND AROUND THE CENTER OF EACH CAPSULES IS BROKEN OR MISSING.

KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION

DISTRIBUTED BY:

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

Package Label

NDC 11822-3374-5

Compare to the active ingredient in Prevacid® 24HR

LANSOPRAZOLE

Delayed-Release Capsules USP, 15 mg

Acid Reducer

TREATS FREQUENT HEARTBURN
MAY TAKE 1 TO 4 DAYS
FOR FULL EFFECT

ACTUAL SIZE
14
ONE 14-DAY COURSE OF TREATMENT CAPSULES

ACTUAL SIZE
14
ONE 14-DAY COURSE OF TREATMENT CAPSULES

1 BOTTLE INSIDE

SATISFACTION GUARANTEE
If you're not satisfied, we'll happily refund your money.

0 11822 33113 5

DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE,
CAMP HILL, PA 17011
www.riteaid.com

PLD-8965A
FD06438

Lot No.:
Exp. Date:

Drug Facts (continued)

Keep product out of high heat and humidity
protect product from moisture
close cap tightly after use

Inactive ingredients
black iron oxide, calcium silicate dihydrate, corn starch, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polyethylene glycol, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), titanium dioxide, yellow iron oxide

Questions or comments?
Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Helsus Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by Helsus Consumer Healthcare, distributor of the Prevacid® 24HR product.

WARNING: EXHAUSTION DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS CRACKED OR MISSING

KEEP OUT OF REACH OF CHILDREN AND PETS. IMPORTANT INFORMATION.

Drug Facts

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Lansoprazole USP, 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
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
heart 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 retching, particularly with heartburn
unexplained weight loss
nausea or vomiting
stomach pain

Ask a doctor or pharmacist before use if you are taking
prescription antifungal or anti-yeast medicines
cyclosporin (heart medicine)
theophylline (asthma medicine)
tacrolimus or mycophenolate mofetil (immune system medicines)
ezetimibe (medicine for HIV infection)
methotrexate (arthritis medicine)

Drug Facts (continued)

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 (1-800-222-1222) 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

Other information
read the directions, warnings and package insert before use
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store at 20° to 25° C (68° to 77° F)

RITE AID Acid Reducer

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3374
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
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3S)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B710)	
AMMONIA (UNII: 5138Q19F1X)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink, green	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	MYL;LD15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3374-5	1 in 1 CARTON	11/29/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11822-3374-7	3 in 1 BOX	11/29/2019	
2		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203187	11/29/2019	

Labeler - Rite Aid Corporation (014578892)

Revised: 7/2021

Rite Aid Corporation