

LANSOPRAZOLE- lansoprazole capsule, delayed release
Rugby Laboratories, Inc.

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 1-800-645-2158

Principal Display Panel

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
- Sodium free

Capsules

Three 14-day Course of Treatment

†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:

Rugby Laboratories

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www.rugbylaboratories.com

Package Label

<p>Drug Facts (continued)</p> <ul style="list-style-type: none">Keep product out of high heat and humidityProtect product from moistureClose cap tightly after use <p>Inactive ingredients black iron oxide, colloidal silicon dioxide, 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, polyoxone 20, potassium hydroxide, propylene glycol, shellac, strong mineralic solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide</p> <p>Questions or comments? Call 1-800-645-2158</p> <p><small>*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.</small></p> <p>TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BLACK BAND AROUND THE CENTER OF EACH CAPSULES IS BROKEN OR MISSING.</p> <p>KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.</p>	<p>NDC 0536-1236-88 Compare to the active ingredient in Prevacid® 24HR†</p> <p>Rugby®</p> <p>Lansoprazole Delayed-Release Capsules USP, 15 mg Acid Reducer</p> <p>Treats Frequent Heartburn</p> <ul style="list-style-type: none">• May take 1 to 4 days for full effect• Sodium free <p>14 Capsules One 14-Day Course of Treatment</p> <p>Actual Size</p> <p>Distributed by: Rugby Laboratories 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 www.rugbylaboratories.com</p> <p>Re-order No. 370729 R-58 Rev. 05/19</p> <p>PLD-45654 FD05742</p> <p>List No.: Exp. Date:</p>	<p>1 BOTTLE INSIDE Actual Size</p> 	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient (in each capsule)</th><th>Purpose</th></tr></thead><tbody><tr><td>Lansoprazole USP, 15 mg</td><td>Acid reducer</td></tr></tbody></table> <p>Use</p> <ul style="list-style-type: none">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 <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to lansoprazole.</p> <p>Do not use</p> <ul style="list-style-type: none">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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">been diagnosed with heartburn over 3 months. This may be a sign of a more serious condition.heartburn with lightheadedness, swelling or dizzinesschest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadednessfrequent chest painunexplained weight lossnausea or vomitingstomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none">warfarin (blood-thinning medicine)prescription antifungal or anti-yeast medicinesdigoxin (heart medicine)theophylline (asthma medicine)tetracycline or erythromycin (antibiotic medicines)statin (cholesterol medicine)zinc (vitamin supplement)methotrexate (arthritis medicine)	Active ingredient (in each capsule)	Purpose	Lansoprazole USP, 15 mg	Acid reducer	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">your heartburn continues or worsensyou need to take this product for more than 14 daysyou need to take more than 1 course of treatment every 4 monthsyou get diarrheayou develop a rash or joint pain <p>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.</p> <p>Directions</p> <ul style="list-style-type: none">adults 18 years of age and olderthis product is to be used once a day (every 24 hours), every day for 14 daysit 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">take every day for 14 daysdo not take more than 1 capsule a dayswallow whole. Do not crush or chew capsules.do not use for more than 14 days unless directed by your doctorRepeat 14-Day Course (if needed)you may repeat a 14-day course every 4 monthsdo not take for more than 14 days or more often than every 4 months unless directed by a doctorchildren under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none">read the directions, warnings and package insert before usekeep the carton and package insert. They contain important information.store at 20° to 25°C (68° to 77°F)
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Lansoprazole USP, 15 mg	Acid reducer							

RUGBY Lansoprazole Delayed-Release Capsules

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1236
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
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: 46N107B71O)	
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	18 mm
Flavor		Imprint Code	MYL;LD15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1236-13	3 in 1 BOX	05/31/2019	
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0536-1236-88	1 in 1 BOX	05/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203187	05/31/2019	

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 11/2020

Rugby Laboratories, Inc.