

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

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**Lansoprazole Delayed Release Capsules USP**

**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
- lansoprazole may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use if you have:**

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools.
- 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**

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

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

**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 healthcare professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away (**1-800-222-1222**).

**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 and warnings before use
- keep the carton. It contains 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**

D&C Red 28, FD&C Blue No.1, FD&C Green 3, FD&C Red 40, gelatin, hydroxypropyl cellulose, iron oxide black, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate 80, sodium lauryl sulphate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide

## **Questions or comments?**

call **1-888-375-3784**

## **Tips For Managing Heartburn**

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Distributed by:

**Dr. Reddy's Laboratories Inc.,**

Princeton, NJ 08540

Issued: 03/2022

## **PRINCIPAL DISPLAY PANEL- Carton Label**

Lansoprazole Delayed- Release Capsules USP, 15 mg

11166001



Drug Facts	Purpose	Drug Facts (continued)
<b>Active ingredient (in each capsule)</b> Lansoprazole USP, 15 mg	Acid Reducer	<ul style="list-style-type: none"> <li>nausea or vomiting</li> <li>stomach pain</li> </ul>
<b>Use</b> <ul style="list-style-type: none"> <li>treats frequent heartburn (occurs 2 or more days a week)</li> <li>not intended for immediate relief of heartburn; the drug may take 1 to 4 days for full effect</li> </ul>		<ul style="list-style-type: none"> <li>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> <li>children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition</li> </ul>
<b>Warnings</b> <ul style="list-style-type: none"> <li>do not use if you are allergic to lansoprazole</li> <li>lansoprazole may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> <li>skin redness</li> <li>blisters</li> <li>rash</li> </ul> </li> <li>if an allergic reaction occurs, stop use and seek medical help right away.</li> </ul>		<ul style="list-style-type: none"> <li>do not use if you have: <ul style="list-style-type: none"> <li>trouble or pain swallowing food, vomiting with blood, or bloody or dark stools.</li> <li>heartburn with lightheadedness, swelling or dizziness</li> <li>chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness</li> <li>frequent chest pain</li> </ul> </li> <li>these may be signs of a serious condition. See your doctor.</li> <li>ask a doctor before use if you have: <ul style="list-style-type: none"> <li>liver disease</li> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>travert, wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> </ul> </li> </ul>
<b>Directions</b> <ul style="list-style-type: none"> <li>adults 18 years of age and older</li> <li>take every day for 14 days</li> <li>do not take more than 1 capsule a day</li> <li>swallow whole. Do not crush or chew capsules.</li> <li>do not use for more than 14 days unless directed by your doctor</li> </ul>		<ul style="list-style-type: none"> <li>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 right away (1-800-222-1222).</li> <li>if it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</li> <li>14-Day Course of Treatment <ul style="list-style-type: none"> <li>swallow 1 capsule with a glass of water before eating in the morning</li> <li>take every day for 14 days</li> <li>do not take more than 1 capsule a day</li> <li>swallow whole. Do not crush or chew capsules.</li> <li>do not use for more than 14 days unless directed by your doctor</li> </ul> </li> </ul>
<b>Other information</b> <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep this carton. It contains important information.</li> <li>store at 20° - 25°C (68° - 77°F)</li> <li>keep product out of high heat and humidity</li> <li>protect product from moisture</li> <li>close cap tightly after use</li> </ul>		
<b>Inactive ingredients</b> (USC Res 28, FD&C Blue No. 1, FD&C Green 3, FD&C Red 40, gelatin, hydroxypropyl cellulose, iron oxide black, low substituted hydroxypropyl cellulose, magnesium carbonate, metacresol, copolymer, polyethylene glycol 6000, polyorbate 40, sodium lauryl sulfate, starch (corn), sucrose, sugar spheres, talc, titanium dioxide)		
<b>Questions or comments?</b> Call 1-888-375-3784		

150099111

NDC 0536-1368-13

**Rugby®**

## Lansoprazole

Delayed-Release Capsules, USP

**15 mg**

Acid Reducer

**42 Capsules**  
Three 14-day courses of treatment

NDC 0536-1368-13  
Compare to the active ingredient in Prevacid® 24HR Capsules\*

**Rugby®**

## Lansoprazole

Delayed-Release Capsules, USP

**15 mg**

Acid Reducer

24 Hour  
Treats Frequent Heartburn  
May take 1 to 4 days for full effect

**42 Capsules**  
Three 14-day courses of treatment

Actual Size



Distributed by:  
**RUGBY® LABORATORIES**  
Indianapolis, IN 46228  
(800) 616-2471  
www.majorpharmaceuticals.com  
Made in India

Rev. 01/23 R-145 Re-order No. 371125



3 05361 36813 5

LOT  
EXP

**3 BOTTLES INSIDE  
42 CAPSULES TOTAL**

**Tips for Managing Heartburn**

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

**TAMPER EVIDENT:** Do not use if foil seal under cap printed with "sealed for your protection" or black band around center of capsule is broken or missing.

**IMPORTANT:** Read the directions and warnings before use. Keep the carton. It contains important information.  
This product is not manufactured or distributed by Perrigo, distributor of Prevacid® 24HR Capsules. Prevacid® is a registered trademark of Helsia Pharmaceuticals U.S.A., Inc.

### PRINCIPAL DISPLAY PANEL - Container Label

**Rugby®** NDC 0536-1368-88

## Lansoprazole

Delayed-Release Capsules, USP

**15 mg**

Acid Reducer

24 Hour  
Treats Frequent Heartburn  
May take 1 to 4 days for full effect

**14 Capsules**  
One 14-day course of treatment

Distributed by: **RUGBY® LABORATORIES**  
Indianapolis, IN 46228  
www.majorpharmaceuticals.com Made in India

Rev. 09/22 R-145  
Re-order No. 371127

3  3  
05361 36888

150089717  
LOT/EXP

**Unvarnished Area**

**PEEL HERE FOR DIRECTIONS**

**Reseal Area**

**Directions**

- adults 18 years of age and older
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**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months

**CONTINUED**

**Hinge**

**Hinge**

**Directions (continued)**

- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
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**Other information**

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- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Questions or comments?**  
Call 1-888-375-3784

# LANSOPRAZOLE

lansoprazole capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1368
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Lansoprazole</b> (UNII: 0K5C5T2QPG) (Lansoprazole - UNII:0K5C5T2QPG)	Lansoprazole	15 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)	
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE (opaque cyan colored cap) , PINK (opaque pink colored body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	3mm
<b>Flavor</b>		<b>Imprint Code</b>	RDY;398
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0536-1368-88	1 in 1 CARTON	10/26/2022	
-		14 in 1 BOTTLE; Type 0: Not a Combination		

1		Product		
2	NDC:0536-1368-13	3 in 1 CARTON	10/26/2022	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202194	10/26/2022	

**Labeler** - Rugby Laboratories, Inc (079246066)

Revised: 6/2023

Rugby Laboratories, Inc