LANSOPRAZOLE- lansoprazole capsule, delayed release
P and L Development of New York Corporation

Drug Facts

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

- you get diarrhea

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. Patients should use the lowest dose and shortest duration of this therapy.**
- 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 **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

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

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release Capsules, 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

Sodium Free

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

TAMPER-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.

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

Distributed by:

PL Developments

Westbury, NY 11590

Product of India

Product Label

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release Capsules, 15 mg

Acid Reducer

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

NDC 59726-019-42

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release Capsules, 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

Sodium Free

Heartburn Relief 24 Hour™
Lansoprazole Delayed-Release Capsules, 15 mg

3 BOTTLES INSIDE

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

42 CAPSULES
Three 14-Day Courses of Treatment

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

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Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590

PLD-B
FC001123

Product of India

3 BOTTLES INSIDE

3 59726 19042 8

Lot No.:

Exp. Date:

Drug Facts

Active ingredient (in each capsule) — **Purpose**
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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

Drug Facts (continued)
- 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

If pregnant or breast-feeding, ask a health professional before use.
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Drug Facts (continued)

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?
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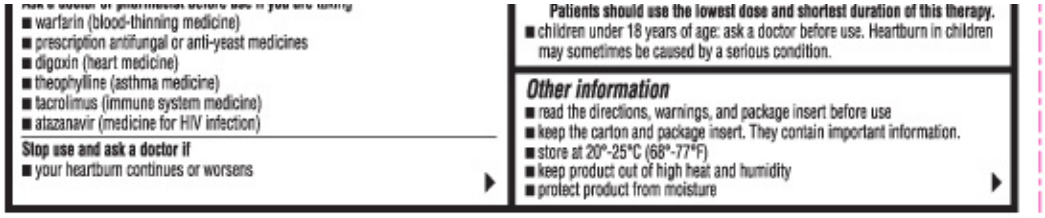
Monday-Friday 9AM-5PM EST



PL Developments Heartburn Relief 24 Hour Capsules

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-019
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, GREEN	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	W140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-019-42	3 in 1 BOX		
1		14 in 1 BOTTLE		
2	NDC:59726-019-14	1 in 1 BOX		
2		14 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202727	01/15/2013	

Labeler - P and L Development of New York Corporation (800014821)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 1/2013 P and L Development of New York Corporation