

LANSOPRAZOLE- lansoprazole capsule, delayed release

H E B

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 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 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).

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

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 type C, 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 toll free: **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Prevacid® 24HR active ingredient*

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release

Capsules USP, 15 mg

Acid Reducer

- **Treats Frequent Heartburn**
- **May take 1 to 4 days for full effect**

Sodium free

CAPSULES

14-DAY COURSE OF TREATMENT

*This product is not manufactured or distributed by Takeda Pharmaceuticals U.S.A., Inc., owner of the registered trademark Prevacid®, or by Perrigo Company plc, distributor of the Prevacid® 24HR product.

TAMPER EVIDENT: DO NOT USE IF TAMPER-EVIDENT INNER SEAL OR BLACK BAND AROUND THE CENTER OF EACH CAPSULES IS MISSING OR BROKEN.

KEEP OUTER CARTON. IT CONTAINS IMPORTANT INFORMATION.

TIPS FOR MANAGING HEARTBURN

- Avoid foods for 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.

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

Package Label

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.
- 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.

<p>Drug Facts</p> <p>Active ingredient (in each capsule) Lansoprazole USP, 15 mg</p> <p>Purpose Acid Reducer</p> <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"> 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> Taking a prescription drug. Acid reducers may interact with certain prescription drugs. 	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <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 right away (1-800-222-1222).</p> <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>Other information</p> <ul style="list-style-type: none"> Read the directions and warnings before use Keep the cap on. It contains important information. Store at 20° to 25°C (68° to 77°F)
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<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Keep product out of high heat and humidity Protect product from moisture Close cap tightly after use <p>Inactive Ingredients black iron oxide, colloid 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 type C, polyethylene glycol, polyacrylate 80, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide</p> <p>Questions or comments? Call toll free: 1-877-753-3835 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not manufactured or distributed by Takeda Pharmaceuticals U.S.A., Inc., owner of the registered trademark Prevacid®, or by Paragon Company plc, distributor of the Prevacid® 24HR product.</small></p> <p>TAMPER EVIDENT: DO NOT USE IF TAMPER EVIDENT UNDER SEAL OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.</p> <p>KEEP OUTER CARTON. IT CONTAINS IMPORTANT INFORMATION.</p>
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Compare to Prevacid® 24HR active ingredient*

NDC:37808-755-14

H-E-B

Heartburn Relief 24 Hour™

Lansoprazole Delayed-Release Capsules USP, 15 mg

Acid Reducer

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

Sodium Free

14 CAPSULES (1 BOTTLE INSIDE)
ONE 14-DAY COURSE OF TREATMENT

actual size

MADE WITH PRIDE AND CARE FOR H-E-B®
SAN ANTONIO, TX 78204 PRODUCT OF INDIA

100% PHARMACEUTICAL GRADE

1 BOTTLE INSIDE

35999 - 2208

0 41220 86388 4

PLD:CS65C FX088237

Lot No.:
Exp. Date:

H-E-B Heartburn Relief

LANSOPRAZOLE

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-755
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: 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: 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	18mm
Flavor		Imprint Code	MYL;LD15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-755-42	3 in 1 BOX	09/30/2019	12/31/2025
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:37808-755-14	1 in 1 BOX	09/30/2019	12/31/2025
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	09/30/2019	12/31/2025

Labeler - H E B (007924756)