

PREVACID 24 HR- lansoprazole capsule, delayed release
L. Perrigo Company

Prevacid 24HR 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
- 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 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

D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, hypermellose, low substituted hydroxypropyl cellulose, mannitol meglumine, methacrylic acid copolymer, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide

Questions or comments?

1-800-864-9649

Package/Label Principal Display Panel

PERRIGO Selfcare™

24HR

PREVACID®

Lansoprazole delayed-release capsules 15 mg / acid reducer

TREATS FREQUENT HEARTBURN

Actual Size

42 CAPSULES

THREE 14-DAY COURSES OF TREATMENT

- MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT
- SODIUM FREE

24 HR PREVACID®

Lansoprazole delayed-release capsules 15 mg / acid reducer

TREATS FREQUENT HEARTBURN

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.

NDC 0113-6117-03



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KEEP THE CARTON. IT CONTAINS
IMPORTANT INFORMATION.



**3 BOTTLES
INSIDE**

42 CAPSULES TOTAL

Actual Size

Distributed By
Perrigo®
Allegan, MI 49010
perrigo.com

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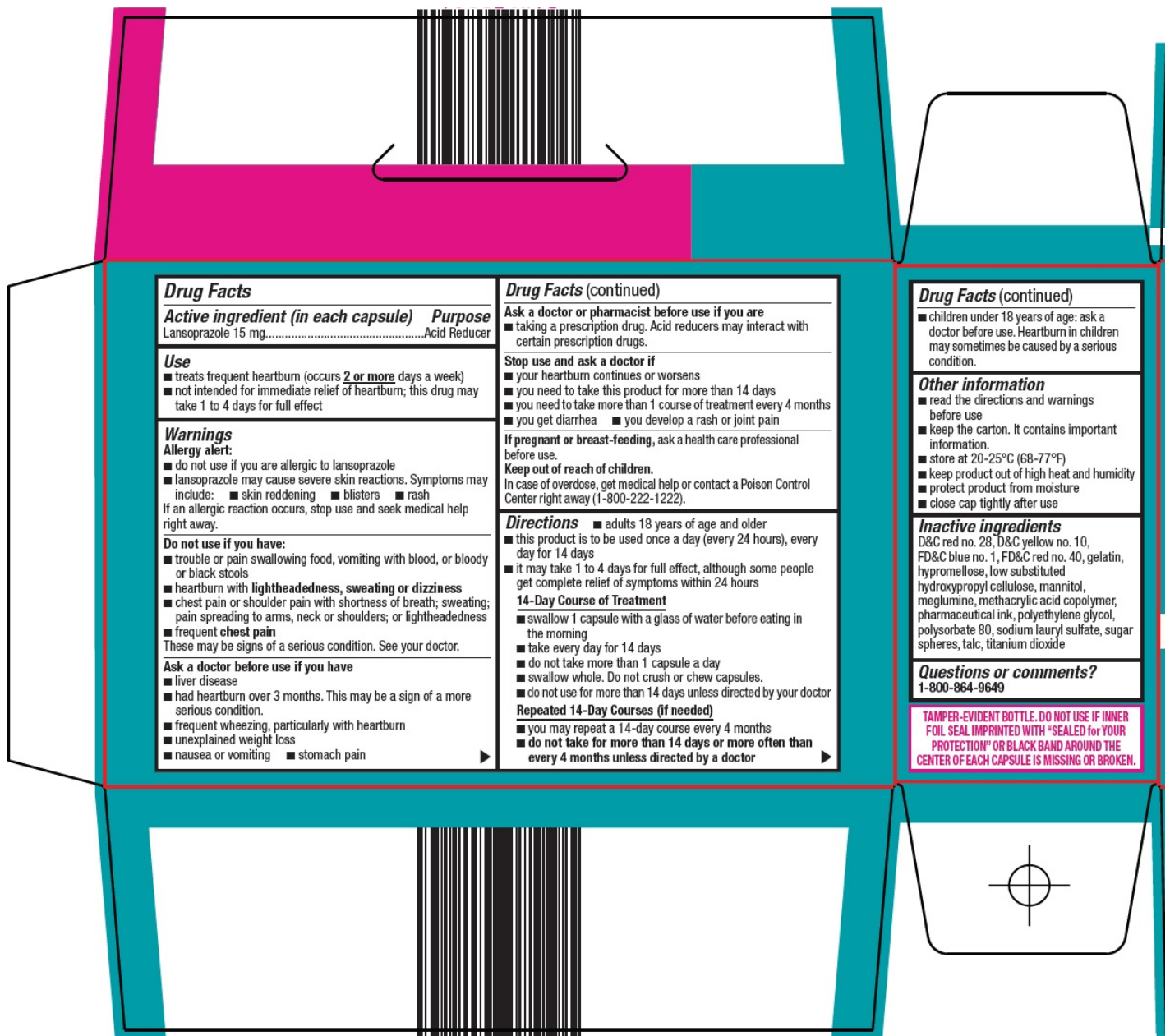
PREVACID® is a registered trademark of Takeda Pharmaceuticals U.S.A., Inc.,
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CODE AREA

54HD7 PB C4



Drug Facts

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Drug Facts (continued)

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Questions or comments?

1-800-864-9649

TAMPER-EVIDENT BOTTLE. DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

PREVACID 24 HR

lansoprazole capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0113-6117 |
| 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. 28 (UNII: 767IP0Y5NH) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| MEGLUMINE (UNII: 6HG8UB2MUY) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SUCROSE (UNII: C151H8M554) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|--------------------|---------------------|----------|
| Color | PINK, GREEN (Teal) | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | 24HR |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0113-6117-01 | 1 in 1 CARTON | 03/30/2023 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:0113-6117-03 | 3 in 1 CARTON | 03/30/2023 | |
| 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 | ANDA202319 | 03/30/2023 | |

Labeler - L. Perrigo Company (006013346)