

**DG HEALTH LANSOPRAZOLE- lansoprazole capsule, delayed release**  
**Dolgenercorp Inc**

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**Dolgenercorp, LLC Lansoprazole 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, hypromellose, 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?**

**1-888-309-9030**

### **Package/Label Principal Display Panel**

DG™ | health

Compare to the active ingredient of Prevacid® 24 HR

Lansoprazole Delayed-Release Capsules, 15 mg

Acid Reducer

- May take 1 to 4 days for full effect
- Sodium free

Treats frequent heartburn

24 HOUR

14 Capsules

One 14-Day Course of Treatment

15 mg

Actual Capsule Size



## DG HEALTH LANSOPRAZOLE

lansoprazole capsule, delayed release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55910-307 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>D&amp;C RED NO. 28</b> (UNII: 7671P0Y5NH)                                   |          |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)                                |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                                  |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                                  |          |
| <b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)                                 |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)                            |          |
| <b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14) |          |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)   |          |
| <b>MEGLUMINE</b> (UNII: 6HG8UB2MUY)  |          |

|   |  |
|---|--|
| <b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J) |  |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)              |  |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                                |  |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                         |  |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                              |  |

| <b>Product Characteristics</b> |             |                     |          |
|--------------------------------|-------------|---------------------|----------|
| <b>Color</b>                   | PINK, GREEN | <b>Score</b>        | no score |
| <b>Shape</b>                   | CAPSULE     | <b>Size</b>         | 15mm     |
| <b>Flavor</b>                  |             | <b>Imprint Code</b> | 24HR     |
| <b>Contains</b>                |             |                     |          |

| <b>Packaging</b> |                  |   |                      |                    |
|------------------|------------------|---|----------------------|--------------------|
| #                | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
| 1                | NDC:55910-307-01 | 1 in 1 CARTON                                     | 06/09/2021           |                    |
| 1                |                  | 14 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA                         | ANDA202319                               | 06/09/2021           |                    |

**Labeler** - Dolgencorp Inc (068331990)