

# **EQUATE LANSOPRAZOLE- lansoprazole tablet, orally disintegrating, delayed release**

**Wal-Mart Stores Inc**

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## **Wal-Mart Lansoprazole Drug Facts**

### **Active ingredient (in each tablet)**

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 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 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**

- take 1 tablet before eating in the morning
- **do not crush or chew tablets**
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

**Repeated 14-Day Course (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, 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**

ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

## **Questions or comments?**

**1-800-719-9260:** weekdays 7:30 AM to 5:00 PM EST

## **Consumer Information**

### **Treats Frequent Heartburn**

### **Lansoprazole**

### **Delayed Release**

### **Orally Disintegrating Tablets 15 mg**

### **acid reducer**

- May take 1 to 4 days for full effect

### **Please read the entire package insert before taking**

### **Lansoprazole Delayed Release Orally Disintegrating Tablets.**

### **Save for future reference.**

### **How Lansoprazole delayed release orally disintegrating tablets Treats Your Frequent Heartburn**

Lansoprazole delayed release orally disintegrating tablets stops acid production at the source - the **pumps** that release acid into the stomach. Lansoprazole delayed release orally disintegrating tablet is taken once a day (every 24 hours), every day for 14 days.

### **What You Can Expect When Taking Lansoprazole delayed release orally disintegrating tablets**

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole delayed release orally disintegrating tablets in the morning before eating. Lansoprazole is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take Lansoprazole delayed release orally disintegrating tablets every day for 14 days to treat your frequent heartburn.

### **Who Should Take Lansoprazole delayed release orally disintegrating tablets**

Adults (18 years and older) with **frequent heartburn** - when you have heartburn 2 or more days a week.

### **Who Should NOT Take Lansoprazole delayed release orally disintegrating tablets**

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

## **How to Take Lansoprazole delayed release orally disintegrating tablets**

### **14-DAY Course of Treatment**

- Take 1 tablet before eating in the morning.
- **Do not crush or chew tablets.**
- Place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- Take every day for 14 days.
- Do not take more than 1 tablet a day.
- Do not use for more than 14 days unless directed by your doctor.
- Do not take this medicine with alcohol.

### **When to Take Lansoprazole delayed release orally disintegrating tablets Again**

You may repeat a 14-day course of therapy every 4 months.

### **When to Talk to Your Doctor**

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

### **Warnings and When to Ask Your Doctor**

**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 or mycophenolate mofetil (immune system medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

### **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).

### **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.

### **Clinical studies prove that lansoprazole effectively treats frequent heartburn**

In three clinical studies, lansoprazole was shown to be significantly better than placebo in treating frequent heartburn.

### **How Lansoprazole delayed release orally disintegrating tablets is Sold**

This medicine is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

### **For Questions or Comments About Lansoprazole delayed release orally disintegrating tablets**

**Call 1-800-719-9260**

**weekdays 7:30 AM to 5:00 PM EST**

Made in Israel

Manufactured by:

Dexcel Pharma Technologies Ltd.

10 Hakidma Street, Yokneam 2069200, Israel

:8U174 00 J3

**Package/Label Principal Display Panel**

equate™

Compare to Prevacid® 24 HR Active Ingredient

Treats Frequent Heartburn

Lansoprazole

Delayed Release Orally Disintegrating Tablets 15 mg

Acid Reducer

24 HOUR

May take 1 to 4 days for full effect

Melts in your mouth

Dissolves without water

Strawberry Flavor

15 mg

42 TABLETS

Three 14-day courses of treatment

Actual Size



## EQUATE LANSOPRAZOLE

lansoprazole tablet, orally disintegrating, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-373
<b>Route of Administration</b>	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
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

<b>COPOVIDONE K25-31</b> (UNII: D9C330MD8B)
<b>CROSPROVIDONE (15 MPA.S AT 5%)</b> (UNII: 68401960MK)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>MALTITOL</b> (UNII: D65DG142WK)
<b>MANNITOL</b> (UNII: 3OWL53L36A)
<b>MEGLUMINE</b> (UNII: 6HG8UB2MUY)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)

### Product Characteristics

<b>Color</b>	WHITE (off white mottled)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	15
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-373-55	42 in 1 CARTON	03/19/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208025	03/19/2019	

**Labeler** - Wal-Mart Stores Inc (051957769)