

LEADER OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release

Cardinal Health 110, LLC. dba Leader

Cardinal Health Omeprazole Delayed Release Orally Disintegrating Tablets, 20 mg Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 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 omeprazole

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 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:

- 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 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

- for 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; 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 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 moisture

Inactive ingredients

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, 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

Package/Label Principal Display Panel

24 HR

Omeprazole

Delayed Release Orally Disintegrating Tablets, 20 mg

Acid Reducer

MELTech™ Melts In Your Mouth

Treats Frequent Heartburn!

Melts in Your Mouth

Dissolves Without Water

Strawberry Flavor

42 TABLETS

Three 14-Day Courses Of Treatment

Actual Size

COMPARE TO PRILOSEC OTC®

100% Money Back Guarantee

CIN 5448568 REV. 3/23



DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43007
www.myleader.com
1-800-200-6313
Essential to Care™ since 1979
Made in Israel

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.
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Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Safety Feature –
Do not use if printed tablet blister unit is open or torn.



Return to place of purchase if not satisfied.



LEADER

NDC 70000-0381-2

24 HR
Omeprazole

Delayed Release Orally Disintegrating Tablets, 20 mg
Acid Reducer



Treats Frequent Heartburn!

Dissolve Tabs
Melts in Your Mouth
Dissolves Without Water

Strawberry Flavor

42 TABLETS

Three 14-Day Courses Of Treatment
May Take 1 to 4 Days for Full Effect



COMPARE TO
PRIOSEC OTC**

100% Money
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LEADER OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0381 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) | OMEPRAZOLE | 20 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSPVIDONE (120 .MU.M) (UNII: 68401960MK) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |

| | |
|--|--|
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM STEARATE (UNII: QU7E2XA9TG) | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | RED (reddish) | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | STRAWBERRY | Imprint Code | 20 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0381-2 | 3 in 1 CARTON | 08/20/2018 | |
| 1 | | 14 in 1 CARTON | | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0381-1 | 14 in 1 CARTON | 08/20/2018 | |
| 2 | | 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 | NDA209400 | 08/20/2018 | |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)