

SUNMARK OMEPRAZOLE- omeprazole tablet, delayed release
Strategic Sourcing Services LLC

McKesson Omeprazole Delayed Release 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 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:

- 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

- swallow 1 tablet with a glass of water before eating in the morning
- 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
- swallow whole. Do not chew or crush tablets

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. 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) and protect from moisture

Inactive ingredients

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260

Principal Display Panel

sunmark[®]

COMPARE TO Prilosec OTC[®]

See Current Drug Facts

omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

TREATS FREQUENT HEARTBURN!

Actual Size

24 HR

14 TABLETS

One 14-day course of treatment

May take 1 to 4 days for full effect



*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

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



COMPARE TO Prilosec OTC®*

NDC 49348-846-46

See Current Drug Facts

omeprazole

Delayed Release Tablets 20 mg Acid Reducer



Actual Size

TREATS FREQUENT HEARTBURN!

24 HR

14 TABLETS

One 14-day course of treatment
May take 1 to 4 days for full effect

9457451 C10

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 light headedness, sweating or dizziness
 - chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or light headedness
 - 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

Drug Facts (continued)

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

- swallow 1 tablet with a glass of water before eating in the morning
- 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
- swallow whole. Do not chew or crush tablets.

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. 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) and protect from moisture

Inactive ingredients

camellia wax, ferric oxided red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, monothanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Made in Israel

McKesson

Another Quality Product Distributed By McKesson
6555 State Highway 161, Irving, TX 75039
Money Back Guarantee
Please visit us at www.sunmarkbrand.com

- 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

SUNMARK OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49348-846 |
| 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 |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MONOETHANOLAMINE (UNII: 5KV86114PT) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STEARATE (UNII: QU7E2XA9TG) | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | BROWN | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | 20 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------|---------------------|----------------------|--------------------|
| | NDC 49348-846 | | | |

| | | | | |
|---|------------------|--|------------|------------|
| 1 | NDC:49348-846-46 | 14 in 1 CARTON | 02/26/2008 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:49348-846-78 | 28 in 1 CARTON | 02/26/2008 | |
| 2 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:49348-846-61 | 42 in 1 CARTON | 02/26/2008 | |
| 3 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:49348-846-55 | 1 in 1 CARTON | 11/16/2010 | 08/01/2013 |
| 4 | | 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 |
|--------------------|--|----------------------|--------------------|
| NDA | NDA022032 | 02/26/2008 | |

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 11/2022

Strategic Sourcing Services LLC