

OMEPRAZOLE MAGNESIUM- omeprazole magnesium capsule, delayed release

Gericare Pharmaceuticals

Gericare Pharmaceuticals Omeprazole 759

Active ingredient (in each capsule)

*Omeprazole delayed-release capsules 20 mg
(equivalent to 20.6 mg omeprazole magnesium)

Purpose

Acid reducer

Uses

- 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

- Omeprazole 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

- 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 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
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush capsules

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

black iron oxide, dibasic calcium phosphate, gelatin, glyceryl monostearate, hypromellose 3 cps, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, methacrylic acid copolymer Type B, microcrystalline cellulose, polysorbate

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
HYPROMELLOSE 2208 (3 MPA.S) (UNII: 9H4L9160BU)
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)
GELATIN (UNII: 2G86QN327L)
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FERRIC OXIDE RED (UNII: 1K09F3G675)
SHELLAC (UNII: 46N107B71O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)

Product Characteristics

Color	pink, white	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	OMP20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-759-14	1 in 1 CARTON	09/01/2016	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:57896-759-28	2 in 1 CARTON	09/01/2016	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:57896-759-42	3 in 1 CARTON	09/01/2016	
3		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	ANDA078878	04/01/2013	

Labeler - Gericare Pharmaceuticals (611196254)

