

OMEPRAZOLE MAGNESIUM- omeprazole magnesium capsule, delayed release
Gericare Pharmaceuticals

Gericare Pharmaceuticals Omeprazole

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

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 80, potassium hydroxide, propylene glycol, red iron oxide, shellac, silicon dioxide, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions?

call 1-888-375-3784

Package label

Drug Facts

Active ingredient (in each capsule)
Omeprazole delayed-release capsules 20 mg (equivalent to 20.6 mg omeprazole magnesium)

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 shoulder; 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

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 (1-800-232-1232).

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.

Reopened 14-Day Course (if needed)

- you may need 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

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- 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, polyd, glycol monostearate, hypromellose 3 cps, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, methacrylic acid copolymer Type B, microcrystalline cellulose, polyacrylate 60, potassium hydroxide, propylene glycol, red iron oxide, shellac, silicon dioxide, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions? call 1-888-375-3764

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

TAMPER EVIDENT: Do not use if foil seal under cap printed with "sealed for your protection" or pink band around center of capsule is broken or missing.

IMPORTANT: Read the directions and warnings before use. Keep the carton. It contains important information.

**This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®. Prilosec OTC® is a registered trademark of AstraZeneca AB.

Distributed by:
GERI-CARE PHARMACEUTICALS CORP.
1650 66th Street
Brooklyn, NY 11204
Made in India

GERI-CARE

Omeprazole

Delayed-Release Capsules

20 mg*

Acid Reducer

24 HR

Treats Frequent Heartburn!

42 Capsules (Safety Sealed)

Three 14-Day Courses of Treatment

May take 1 to 4 days for full effect

Compare to the active ingredient in Prilosec OTC***

NDC 57896-759-42

3 Bottles Inside



Actual Size



1 5 0 0 7 7 1 8 3

R072019



3 57896 75942 1

OMEPRAZOLE MAGNESIUM

omeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-759
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20.6 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM OXIDE (UNII: 3A3U0G171G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
RAW SUGAR (UNII: 8M707QY5GH)	
TALC (UNII: 7SEV7J4R1U)	
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 MPAS) (UNII: 9H4L916OBU)	
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: OP1R32D6IU)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SHELLAC (UNII: 46N107B710)	
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)

Registrant - Gericare Pharmaceuticals (611196254)

Revised: 12/2019

Gericare Pharmaceuticals