OMEPRAZOLE MAGNESIUM- omeprazole magnesium capsule, delayed release
Chain Drug Marketing Association

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
- 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.

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 sulphate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions

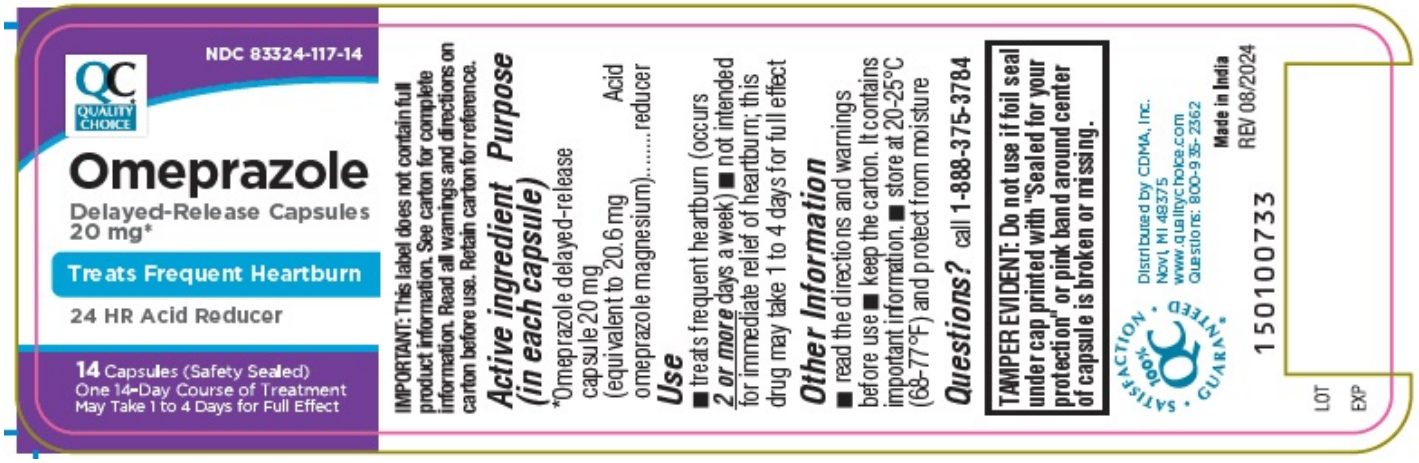
call **1-888-375-3784**

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

Carton Label

Bottle Label



OMEPRAZOLE MAGNESIUM

omeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83324-117(NDC:55111-397)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (omeprazole - UNII:KG60484QX9)	omeprazole	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
Gelatin (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE 2208 (3 MPA.S) (UNII: 9H4L916OBU)	
Magnesium Oxide (UNII: 3A3U0GI71G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)	
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)	
RAW SUGAR (UNII: 8M707QY5GH)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Sodium Lauryl Sulfate (UNII: 368GB5141J)	

Product Characteristics

Color	WHITE, PINK	**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:83324-117-14	1 in 1 CARTON	11/01/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83324-117-42	3 in 1 CARTON	11/01/2024	
2		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	01/01/2016	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 7/2025 Chain Drug Marketing Association