

**OMEPRAZOLE- omeprazole magnesium capsule, delayed release**  
**CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS Pharmacy, Inc. Omeprazole Drug Facts**

**Active ingredient (in each capsule)**

Omeprazole delayed-release capsule 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 (1-888-222-1222).

**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
- FDA approved dissolution test specifications differ from USP

## **Inactive ingredients**

FD&C yellow # 6, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

## **Questions or comments?**

**1-800-719-9260**

## **Package/Label Principal Display Panel**

CVS Health®

Compare to the active ingredient in Prilosec OTC®

MINI CAPSULES

Treats FREQUENT Heartburn!

TRIPLE PACK

3 X 14 COUNT BOTTLES INSIDE

Omeprazole

DELAYED-RELEASE CAPSULES, 20 mg

Acid reducer

See current Drug Facts

Actual Size

24 HOUR

42 MINI CAPSULES

Three 14-day courses of treatment

May take 1 to 4 days for full effect



# OMEPRAZOLE

omeprazole magnesium capsule, delayed release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-271
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MUJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B710)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
Product Characteristics				
Color	WHITE, ORANGE		Score	no score
Shape	CAPSULE		Size	14mm
Flavor			Imprint Code	24S
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-271-03	3 in 1 CARTON	04/01/2025	
1	NDC:51316-271-01	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		ANDA216096	04/01/2025	

**Labeler -** CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 4/2025

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED