

OMEPRAZOLE- omeprazole capsule, delayed release
CVS Pharmacy, Inc

Omeprazole

Drug Facts

Active ingredient (in each capsule)

*Omeprazole delayed-release capsule 20 mg (equivalent to 20.6 mg omeprazole magnesium, USP)

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 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). [See USP controlled room temperature]. Protect from moisture

Inactive ingredients

FD&C blue #1, FD&C red #40, ferrousferrous oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium stearate, methacrylic acid copolymer, mono and di glycerides, polyethylene glycol 6000, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sodium stearyl fumarate, sugar spheres (starch and sucrose), talc, titanium dioxide and triethyl citrate

Questions?

Call toll-free Monday to Friday 8:30 am to 5 pm EST at **1800-406-7984**.

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 20 mg Capsule Bottle Carton

CVS Health®

Compare to the active
ingredient in Prilosec OTC®**

NDC 51316-061-28

DOUBLE PACK
2 X 14 COUNT BOTTLES INSIDE

Treats Frequent Heartburn!

Omeprazole
24
HOUR

DELAYED-RELEASE
CAPSULES 20 mg*

Acid reducer
May take 1 to 4 days
for full effect

Actual Size

28 CAPSULES
Two 14-day courses of treatment

Package Contains
Two Bottles

CVSHealth.

Treats Frequent Heartburn!
Omeprazole

DELAYED-RELEASE
CAPSULES 20 mg*
Acid reducer



Drug Facts (continued)

magnesium carbonate, magnesium stearate, methacrylic acid copolymer, mono and di glycerides, polyethylene glycol 6000, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sodium stearyl fumarate, sugar spheres (starch and sucrose), talc, titanium dioxide and triethyl citrate

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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 FEATURES: Do not use if foil seal under cap printed with "sealed for your protection" or transparent band around center of capsule is missing, torn or broken.

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CVSHealth.

Compare to the active ingredient in Prilosec OTC^{®**}
NDC 51316-061-28

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Omeprazole

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**All trademarks are property of their respective owners. This product is not affiliated with the makers of Prilosec OTC[®].

#488027

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Woonsocket, RI 02895
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CVS.com[®]
1-800-SHOP CVS
V-37475



0221

Batch No.

Expiration Date:



5217920

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Drug Facts (continued)

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5217920



OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-061
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	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQV0RT)				
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)				
MAGNESIUM CARBONATE (UNII: 0E53J927NA)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
STARCH, CORN (UNII: O8232NY3SJ)				
SUCROSE (UNII: C151H8M554)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)				
Product Characteristics				
Color	PINK	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	RG;49	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-061-28	2 in 1 CARTON	01/09/2021	
1		28 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	ANDA210593	01/09/2021		

Labeler - CVS Pharmacy, Inc (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(51316-061)

Revised: 4/2021

CVS Pharmacy, Inc