

OMEPRAZOLE- omeprazole capsule, delayed release
Walgreen Company

Walgreen Co. 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 (1-800-222-1222).

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

- 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

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Prilosec OTC®

Mini Capsules

Omeprazole

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour

Treats FREQUENT Heartburn!

42 MINI CAPSULES

THREE 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

ACTUAL SIZE

SEE CURRENT DRUG FACTS

Walgreens

Mini Capsules

Omeprazole

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

SAFETY FEATURE – DO NOT USE IF PRINTED FOIL SEAL UNDER CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING

Walgreens

Compare to the active ingredient in Prilosec OTC™



Mini Capsules

Omeprazole

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour

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42

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THREE 14-DAY COURSES OF TREATMENT
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ACTUAL SIZE

SEE CURRENT DRUG FACTS



Walgreens

Mini Capsules

Omeprazole

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour Treats FREQUENT Heartburn!

14 MINI CAPSULES NOT FOR INDIVIDUAL SALE
ONE 14-DAY COURSE OF TREATMENT
MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

ACTUAL SIZE
3 BOTTLES INSIDE

¹Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

^{††}This product is not manufactured or distributed by AstraZeneca AB, owner of the registered trademark Prilosec OTC®. NDC 0363-4099-03

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MADE IN ISRAEL

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REV-0925

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OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4099
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: 6HG8UB2MUY)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B71O)	
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	57S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4099-03	3 in 1 CARTON	03/06/2026	
1	NDC:0363-4099-01	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	03/06/2026	

Labeler - Walgreen Company (008965063)