OMEPRAZOLE- omeprazole magnesium 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 <u>2 or more</u> 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

Walgreens • WALGREENS • PHARMACIST RECOMMENED 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 ACTUAL SIZE THREE 14-DAY COURSES OF TREATMENT MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT SEE CURRENT DRUG FACTS



24SD7 94 C1

Drug Facts Active ingredient (in each capsule) Purpose Omeprazole delayed-release capsule 20 mg (equivalent to 20.6 mg omeprazole magnesium)Acid reducer Use Active ingredient (in each capsule) Acid reducer Use • treats frequent heartburn (occurs <u>2 or more</u> 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. Donot use if you have: • trouble or pain swallowing food, vomiting with blood, or bloody or black stools • heartburn with lightheadedness, sweating or dizziness • heartburn with sightheadedness, sweating or dizziness	Drug Facts (continued) Ask a doctor or pharmacist before use if you are taking a prescription drugs. Stop use and ask a doctor if: you heartburn continues or worsens you need to take this product for more than 14 days you get diarrhea you get diarrhea you get diarrhea you get of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Directions I for adults 18 years of age and older I 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	Drug Facts (continued) 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 • FDA cyplow # 6, ferric oxide, gelatin, glyceryl monostearate, 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
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		W3ORG1023-F

OMEPRAZOLE					
omeprazole magnesium caps	sule, delayed release				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:0363-6089		-6089	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of Strength Str		Strength	
OMEPRAZOLE MAGNESIUM (UNII UNII:KG60484QX9)	: 426QFE7XLK) (OMEPRAZ O	LE -	OMEPRAZO	LE	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: 2300U9XXE4)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MEGLUMINE (UNII: 6HG8UB2MUY)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
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	245
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0363-6089- 03	3 in 1 CARTON	04/09/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
	NDC:0363-6089- 01	14 in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2024	
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Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA216096	04/09/2024	

Labeler - Walgreen Company (008965063)

Revised: 4/2024