

OMEPRAZOLE MAGNESIUM- omeprazole magnesium capsule, delayed release

Dr. Reddy's Laboratories Limited

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 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

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 sulfate, 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

Revised: 10/2022

Bottle Label

Dr.Reddy's

NDC 55111-397-52

Treats Frequent Heartburn! 24 HR

Omeprazole

Delayed Release- Capsules

20 mg*

ACID REDUCER

14 Capsules(Safety Sealed)

One 14-Day Course of Treatment

May take 1 to 4 days for full effect

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14 Capsules (Safety Sealed)
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IMPORTANT: This label does not contain full product information. See carton for complete information. Read all warnings and directions on carton before use. Retain carton for reference.

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Questions? call 1-888-375-3784

TAMPER EVIDENT: Do not use if foil seal under cap printed with "Sealed for your protection" or pink band around center of capsule are broken or missing.

Distributed by: Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540

Revised: 10/2022

1500XXXXXX

LOT
EXP

Carton Label

Dr.Reddy's

NDC 55111-397-52

Compare to the active ingredient in Prilosec OTC®**

Treats Frequent Heartburn! 24 HR

Omeprazole

Delayed Release- Capsules

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ACID REDUCER

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Drug Facts (continued)

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Dr.Reddy's NDC 55111-397-52
Compare to the active ingredient in Prilosec OTC®

Treats FREQUENT Heartburn! 24 HR

See current Drug Facts

Omeprazole

Delayed-Release Capsules
20 mg*

ACID REDUCER

14 Capsules (Safety Sealed)
One 14-Day Course of Treatment
May take 1 to 4 days for full effect

Distributed by: Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540

Made in India
Revised: 10/2022

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LOT _____

EXP _____

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- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

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OMEPRAZOLE MAGNESIUM

omeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE 2208 (3 MPA.S) (UNII: 9H4L9160BU)	
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)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
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)	

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:55111-397-52	1 in 1 CARTON	03/01/2010	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-397-27	2 in 1 CARTON	03/01/2010	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-397-33	3 in 1 CARTON	03/01/2010	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-397-39	3 in 1 CARTON	09/01/2015	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-397-28	2 in 1 CARTON	03/01/2010	
	NDC:55111-397-			

5	NDC:55111-397-74	2 in 1 CARTON		
5		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:55111-397-42	3 in 1 CARTON	03/01/2010	
6	NDC:55111-397-74	2 in 1 CARTON		
6		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078878	03/01/2010	

Labeler - Dr. Reddy's Laboratories Limited (650562841)

Revised: 11/2022

Dr. Reddy's Laboratories Limited