

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium tablet, delayed release

Dr. Reddys Laboratories Inc

Drug Facts

Active ingredient(in each tablet)

*Esomeprazole 20 mg

(Each delayed-release tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate, USP)

Purpose

Acid reducer

Uses

- 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 esomeprazole
- Esomeprazole 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 lightheadness.
- 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

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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

- adults 18 years of age and older.
- this product is to be used once a day (every 24 hours), every day for 14 days.
- may take 1 to 4 days for full effect

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning.
- take every day for 14 days
- do not take more than 1 tablet a day
- swallow whole. Do not crush or chew tablets
- do not use for more than 14 days unless directed by your doctor

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 before use. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read directions and warnings before use.
- keep the carton. It contains important information

Storage

- store at 20°C to 25°C (68°F to 77°F)

Inactive ingredients

crospovidone, glyceryl monostearate, hypromellose, iron oxide red, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polysorbate 80, simethicone, sodium stearyl fumarate, sugar spheres (contains sucrose and maize starch), talc, titanium dioxide, triethyl citrate

Questions

call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime
- Do not lie flat or bend over soon after eating
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach
- If you are overweight, lose weight
- If you smoke, quit smoking.

Distributor:

Dr. Reddy's Laboratories Inc.,

Princeton, NJ 08540

Made in India

Issued: 10/2023

Principal Display Panel

Container 14's count:



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75907-119
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Esomeprazole Magnesium (UNII: R6DXU4WAY9) (Esomeprazole - UNII:N3PA6559FT)	Esomeprazole	20 mg

Inactive Ingredients

Ingredient Name	Strength
Crospovidone (UNII: 2S7830E561)	

Glyceryl Monostearate (UNII: 230OU9XXE4)
Hypromelloses (UNII: 3NXW29V3WO)
Ferric Oxide Red (UNII: 1K09F3G675)
Magnesium Stearate (UNII: 70097M6I30)
Mannitol (UNII: 3OWL53L36A)
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)
Cellulose, Microcrystalline (UNII: OP1R32D61U)
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)
Polysorbate 80 (UNII: 6OZP39ZG8H)
Dimethicone 350 (UNII: 2Y53S6ATLU)
Sodium Stearyl Fumarate (UNII: 7CV7WJK4UI)
Sucrose (UNII: C151H8M554)
Talc (UNII: 7SEV7J4R1U)
Titanium Dioxide (UNII: 15FIX9V2JP)
Triethyl Citrate (UNII: 8Z96QXD6UM)

Product Characteristics			
Color	PINK (light pink)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	I
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75907-119-52	1 in 1 CARTON	12/30/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:75907-119-27	2 in 1 CARTON	12/30/2023	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:75907-119-33	3 in 1 CARTON	12/30/2023	
3		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	ANDA211571	12/30/2023	

Labeler - Dr. Reddys Laboratories Inc (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	pack(75907-119)

Revised: 12/2023

Dr. Reddys Laboratories Inc