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 <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 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 or comments?

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

Tips for Managing Heartbun

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chDistocolate, 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.,

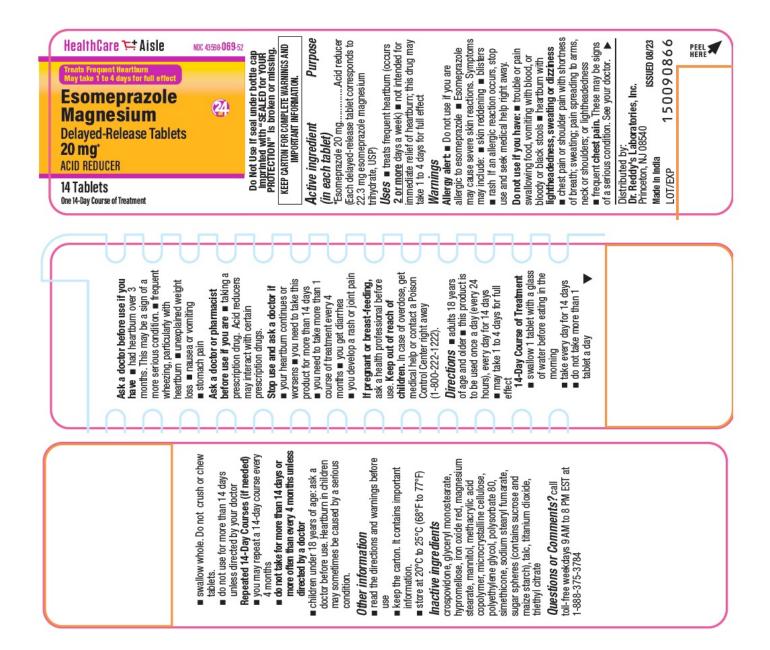
Princeton, NJ 08540

Made in India

Issued: 10/2023

Principal Display Panel

Container label 14count:



Carton 14's count:

			Esomeprazole Magnesium Delayed-Release Tablets, 20 mg [*] ACID REDUCER	active ingredient in Recium? 24HR Tablets**	
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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 ack a doctor if your heartburn confirmes or worsens	microsyntalline cellulose, polyithylene ghoci, polyisofidate 80, simetticore, social estary finanziae, sigar appressi contains surrose and mais starch), tale, Itanium dioxide, tixtatyl chrate Questions or comments? call holl-nee weekdays 9 AM to 8 PM EST at 1-888-378-3784		42 Tablets Three 14-Day Courses of Treatment	Actual Size	Actual Size
III			3 43598 06942 5		

esomeprazole magnesium t	ablet, delayed release					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sour	m Code (Source) NDC		C:43598-069	
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Sucrose (UNII: C15)	1H8M554)				
Talc (UNII: 7SEV7J4	R1U)				
Titanium Dioxide	(UNII: 15FIX9V2JP)				
Triethyl Citrate (U	NII: 8Z96QXD6UM)				
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Marketing	Information				
Marketing Marketing Category	I nformation Application Number or Mon Citation	ograph	Marketing Start Date	Marketing End Date	

Labeler - Dr. Reddys Laboratories Inc (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	pack(43598-069)

Revised: 1/2024

Dr. Reddys Laboratories Inc