

# **ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release**

**Dr. Reddy's Laboratories Inc**

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**Drug Facts**

## **Active ingredient(s) in each capsule**

\* Esomeprazole 20 mg

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

## **Purpose**

Acid reducer

## **Use(s)**

- 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 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**

- 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 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
- swallow whole. Do not crush or chew capsules
- 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.
- store at 20°C to 25°C (68°F to 77°F)
- this product meets USP Dissolution Test 3

## **Inactive ingredients**

FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, polysorbate 80, potassium hydroxide, propylene glycol, shellac, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

## **Questions or comments**

call toll-free weekdays 8 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: 06/2024

## **Principal Display Panel**

Container Labeling

Top  
(PNL 1)

Dr. Reddy's  NDC 43698-327-02  
Treats Frequent Heartburn  
May take 1 to 4 days for full effect

**Esomeprazole  
Magnesium**  
Delayed-Release Capsules, USP  
20 mg\*

**ACID REDUCER** 24

14 Capsules  
One 14-day course of treatment

**TAMPER EVIDENT FEATURES: Do Not Use**  
If seal under the cap imprinted with  
"SEALED FOR YOUR PROTECTION" or  
black band around the center of each  
capsule is broken or missing.

**KEEP CAPSULES FROM COMPLETE WARMINGS  
AND IMPORTANT INFORMATION**

**Active Ingredient  
(In each capsule)**  
Esomeprazole 20 mg Acid reducer  
(Each delayed-release capsule  
corresponds to 22.5 mg esomeprazole  
magnesium trihydrate, USP)

**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  
redness ■ 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

Distributed by:  
Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540  
REV. 06/2024 Made in India  
LOPEP 150100820

**FREE  
HERE** 

0.375

Top Inside  
(PNL 2)

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 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)

0.875

Bottom  
(PNL 3)

**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 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
- swallow whole. Do not crush or chew  
capsules.
- 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 the  
directional warnings before use ■ keep the  
carton, contents impervious to moisture.  
■ store at 20°-25°C (68°F-77°F) ■ this  
product meets USP Dissolution Test 3

**Inactive ingredients**  
RiSO Blue #1, ferrous ferric oxide, cellu-  
lose, glyceryl monostearate, hydroxypropyl  
cellulose, hydroxypropylcellulose, magnesium  
stearate, methacrylic acid  
copolymer, polyacrylate-80, potassium  
hydroxide, croscarmellose, stearic  
acid, titanium dioxide and triethyl citrate.

**Questions or comments?** call  
toll-free weekdays 8 AM to 8 PM EST at  
1-888-375-3784

Container Carton Labeling



## ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-327
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ESOMEPRAZOLE MAGNESIUM</b> (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SUCROSE (UNII: C151H8M554)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
SHELLAC (UNII: 46N107B71O)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

## Product Characteristics

Color	BLUE (light blue cap and dart blue body)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	RDY;496
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-327-52	1 in 1 CARTON	03/01/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-327-27	2 in 1 CARTON	03/01/2025	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-327-33	3 in 1 CARTON	03/01/2025	
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	ANDA207198	03/01/2025	

**Labeler** - Dr. Reddy's Laboratories Inc (802315887)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited - FTO 3		918608162	manufacture(43598-327) , analysis(43598-327)

## Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	pack(43598-327)

Revised: 6/2024

Dr. Reddy's Laboratories Inc