

**ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium tablet, delayed release**  
**Dr. Reddys Laboratories Inc**

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**Drug Facts**

**Active ingredient(s)**

\*Esomeprazole 20 mg

(Each delayed-release tablet 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

**Do not use**

- 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**

- 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**

- 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

**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 to 25°C (68 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: 0420

**Principal Display Panel**

Container 14's count:

Dr. Reddy's NDC 43596-469-52  
Treats Frequent Heartburn  
May take 1 to 4 days for full effect

## Esomeprazole Magnesium

Delayed-Release Tablets  
20 mg\*

**ACID REDUCER**

24 hr

14 Tablets  
Once 14-Day  
Course of Treatment

Do not use this seal under the cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing. **KEEP CAP OFF FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.**

Drug Facts	Active ingredient	Purpose
<p>(in each tablet)</p> <ul style="list-style-type: none"> <li>• Esomeprazole 20 mg...Acti nedar</li> <li>(Each delayed-release tablet contains 20 mg of esomeprazole magnesium trihydrate USP)</li> </ul> <p>Uses • Treats frequent heartburn (occurs 2 or more days a week)</p> <ul style="list-style-type: none"> <li>• not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> <p>Warnings</p> <ul style="list-style-type: none"> <li>• Allergy alert: Do not use if you are allergic to esomeprazole. Do not use if you have: <ul style="list-style-type: none"> <li>• trouble or pain swallowing food, vomiting with blood, or bloody or black stools</li> <li>• heartburn with light-headedness, sweating or dizziness</li> <li>• chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck, or shoulders, or lightheadedness</li> </ul> </li> </ul>	<p>Esomeprazole Magnesium</p>	<p>Treats Frequent Heartburn</p>

DISTRIBUTED BY:  
Dr. Reddy's Laboratories Inc.,  
Parsippany, NJ 08854  
Made in India

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PEEL HERE

**Drug Facts (continued)**

- 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. There may be a sign of a more serious condition.
  - frequent wheezing, particularly with heartburn
  - it is painful to lift things
  - 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 worsens
  - 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, or if you plan to breast-feed your baby
- Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away (1-800-522-1222).

**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

**Drug Facts (continued)**

- 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 the directions and warnings before use
- keep the carton, it contains important information.
- store at 20° to 25°C (68° to 77°F)

**Inactive ingredients**  
croscollonite, glyceryl methacrylate, hypromellose, iron oxide red, magnesium stearate, mannitol, malic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyethylene glycol, sodium lauryl sulfate, sugar spheres (contains sucrose and maltodextrin), talc, titanium dioxide, triethyl citrate

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

Carton 14's count:



**Drug Facts (continued)**

- 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 (1-800-222-1222).

**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
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  - do not take more than 1 tablet a day
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**Drug Facts (continued)**

**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 directions and warnings before use
- keep the carton. It contains important information.
- store at 20 to 25°C (68 to 77°F)

**Inactive ingredients**  
croscellose, glyceryl monostearate, hydroxyethylcellulose, iron oxide red, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, sodium alginin, 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 1-888-370-3784

**WARNING: Do not use if you see both cap prints with "WARNING FOR YOUR PROTECTION" in circles or missing. KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.**

\*This product is not manufactured or distributed by Pfizer Inc., distributor of Nexium® 24HR. Nexium® is a registered trademark of AstraZeneca AB.

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Made In India  
Issued: 04/20

**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.

Clinically proven to treat frequent heartburn

**Dr. Reddy's**  NDC 43598-469-52  
Compare to the active ingredient in Nexium® 24HR Tablets\*\*

Treats Frequent Heartburn  
May take 1 to 4 days for full effect

**Esomeprazole Magnesium**

**Delayed-Release Tablets 20 mg\***

**ACID REDUCER**



**14 Tablets**  
One 14-Day Course of Treatment

**1 BOTTLE INSIDE**

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Esomeprazole 20 mg.....	Acid reducer

(Each delayed-release tablet comes parafin to 22.3 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

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; swelling; 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



LOT  
EXP

Carton 28s count



Carton 42s count



# ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium tablet, delayed release

## Product Information



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-469
<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
<b>Crospovidone</b> (UNII: 2S7830E561)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Mannitol</b> (UNII: 3OWL53L36A)	
<b>Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A</b> (UNII: NX76LV5T8J)	
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Dimethicone 350</b> (UNII: 2Y53S6ATLU)	
<b>Sodium Stearyl Fumarate</b> (UNII: 7CV7WJK4U)	
<b>Sucrose</b> (UNII: C151H8M554)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Triethyl Citrate</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	PINK (light pink)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	469
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-469-52	1 in 1 CARTON	11/15/2020	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-469-28	2 in 1 CARTON	11/15/2020	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-469-42	3 in 1 CARTON	11/15/2020	
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
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ANDA	ANDA211571	11/15/2020	
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**Labeler** - Dr. Reddys Laboratories Inc (802315887)

Revised: 7/2020

Dr. Reddys Laboratories Inc