

**ACID REDUCER- esomeprazole magnesium tablet, delayed release  
Cardinal Health (Leader) 70000**

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**Esomeprazole Magnesium Delayed-Release Capsules 20 mg - Actavis**

***Drug Facts***

***Active ingredient (in each tablet)***

Esomeprazole 20 mg

(\*Each delayed-release tablet corresponds to 22.25 mg esomeprazole magnesium, USP (trihydrate))

***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 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**

- 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 (1-800-222-1222) right away.

***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 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**

black iron oxide, colloidal silicon dioxide, croscopovidone, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium stearate, methacrylic acid - ethyl acrylate copolymer dispersion, microcrystalline cellulose, mono- and di-glycerides, polyethylene glycol, polysorbate 80, propylene glycol, red iron oxide, shellac glaze, sodium lauryl sulfate, sodium stearyl fumarate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide

**Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

**Principal Display Panel**

COMPARE TO NEXIUM® 24 HR active ingredient†

24-hour

**Esomeprazole Magnesium**

Delayed-Release Tablets, 20 mg\* | Acid Reducer

Treats Frequent Heartburn

May Take 1 to 4 days for Full Effect

TABLETS

One 14-Day Course of Treatment

**SEE NEW WARNING INFORMATION**

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Nexium® 24HR.

**TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING.**

**KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

**Package label**

**Drug Facts**

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

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- frequent wheezing, particularly with heartburn
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- nausea or vomiting
- stomach pain

**Drug Facts (continued)**

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**Questions or comments?**  
Call 1-877-753-3838 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Nexium® 24HR.

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**KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.**

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NDC 70000-0095-1

**24 Hour**

# Esomeprazole Magnesium

Delayed-Release Tablets, 20 mg\* | Acid Reducer

Treats Frequent Heartburn  
May Take 1 to 4 Days for Full Effect

**14 TABLETS (1 Bottle Inside)**  
One 14-Day Course of Treatment

SEE NEW WARNING INFORMATION



Actual Size

**COMPARE TO NEXIUM® 24HR**  
active ingredient\*

100% Money Back Guarantee

**24 Hour**

# Esomeprazole Magnesium

Delayed-Release Tablets, 20 mg\* Acid Reducer

**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.

SEE NEW WARNING INFORMATION

**CardinalHealth™**

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6515  
Essential to Care™ since 1879

Product of India

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CIN 5715714 REV. 08/23



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## LEADER Acid Reducer

## ACID REDUCER

esomeprazole magnesium tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0095
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98RO82HJ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED</b> (UNII: 2165RE0K14)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

<b>Product Characteristics</b>			
<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	EL
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0095-1	1 in 1 CARTON	04/30/2021	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0095-2	3 in 1 CARTON	04/30/2021	
2		1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212088	04/30/2021	

**Labeler** - Cardinal Health (Leader) 70000 (063997360)