

**ACID REDUCER- esomeprazole magnesium tablet, delayed release**  
**P & L Development, LLC**

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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 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, crospovidone, 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 the active ingredient in **Nexium® 24 Hour†**

see new warning information

24-hour

esomeprazole magnesium

delayed-release tablets, 20 mg\*

acid reducer

treats frequent heartburn

may take 1 to 4 days for full effect

†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 IMPORTANT INFORMATION.**

Distributed by:

### **PL Developments**

200 Hicks Street

Westbury, NY 11590

### **Package label**



<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: 3WJQ0SDW1A)	
<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)	

### Product Characteristics

<b>Color</b>	white (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>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-056-14	1 in 1 CARTON	12/31/2020	06/30/2026
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59726-056-42	3 in 1 CARTON	12/31/2020	06/30/2026
2		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212088	12/31/2020	06/30/2026

**Labeler** - P & L Development, LLC (800014821)