

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

**Amerisource Bergen**

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

## ***Drug Facts***

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

\*Esomeprazole 20 mg  
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)

### ***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 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 the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F)
- Meets USP dissolution test 2

**Inactive ingredients**

colloidal silicon dioxide, FD&C blue no.1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

**Questions or comments?**

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

**Distributed By**  
**AmerisourceBergen**  
**1 West First Avenue**  
**Conshohocken, PA 19428**  
**Questions or Concerns?**

**[www.mygnp.com](http://www.mygnp.com)**

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsules Container Label)**

**Rx**  
**GOOD**  
**NEIGHBOR**  
**PHARMACY®**

**NDC 46122-736-74**

**24HR**

**Esomeprazole Magnesium**  
**delayed-release capsules USP 20 mg\***

***Acid Reducer***

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

***Capsules***

**14 Capsules** One 14-day course of treatment

# Top Ply

**Good Neighbor Pharmacy** NDC 46122-736-74

**24 HR**  
**Esomeprazole Magnesium**  
delayed-release capsules USP 20 mg\*

**Acid Reducer**

Treats Frequent Heartburn  
May take 1 to 4 days for full effect  
14 Capsules | One 14-day course of treatment

**Cap**

Do not use if seal imprinted with **SEALED for YOUR PROTECTION** under the bottle cap is broken or missing.

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

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Conshohocken, PA 19428  
Questions or Concerns?  
[www.mygrp.com](http://www.mygrp.com)  
Made in India Code: TS/DRUGS/22/2009

**SATISFACTORY GUARANTEE**

**Active ingredient (in each capsule)**  
\*Esomeprazole 20 mg  
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)

**Purpose**  
Acid reducer

P1432012 LM-5078

Lift Here

No Varnish

## Top Ply (Page #1)

**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 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).

P1432012 LM-5078

## Back of Top Ply (Page #2)

# Bottom Ply

## Base (Page #3)

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 directions and warnings before use; keep the carton. It contains important information. store at 20-25°C (68-77°F); Meets USP dissolution test 2. **Inactive ingredients:** colloidal silicon dioxide, FD&C blue no. 1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polyorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide. **Questions or comments?** call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

P1432012 LM-5078

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsules Container Carton)**

**Rx**  
**GOOD**  
**NEIGHBOR**  
**PHARMACY®**

**Compare to Nexium® 24HR**

active ingredient\*\*

NDC 46122-736-74

See new warning information

24HR

**Esomeprazole Magnesium**  
delayed-release capsules USP 20 mg\*

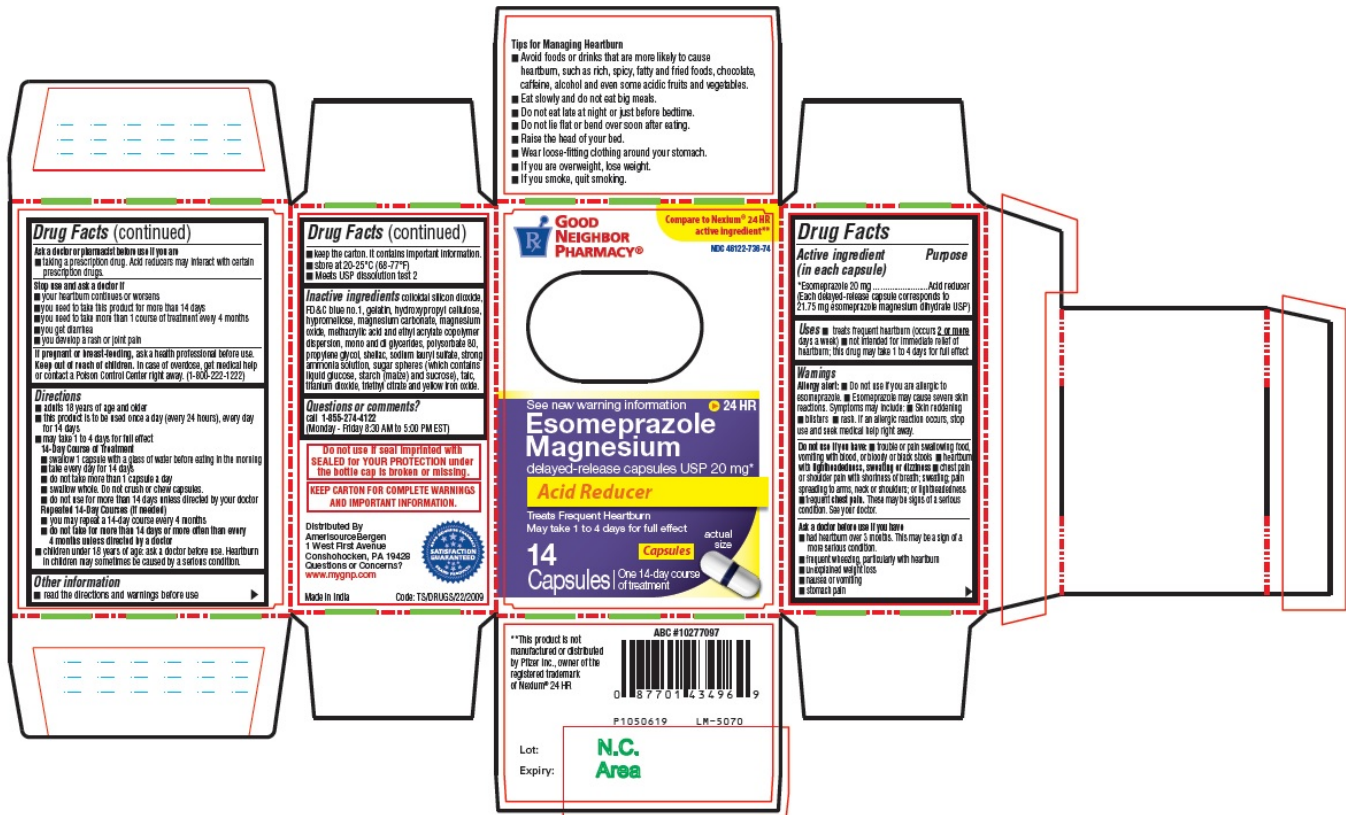
**Acid Reducer**

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

**Capsules**

**actual  
size**

**14  
Capsules** One 14-day course of treatment



## ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-736
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ESOMEPRAZOLE MAGNESIUM DIHYDRATE</b> (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	I81
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-736-74	1 in 1 CARTON	08/04/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:46122-736-03	2 in 1 CARTON	07/19/2023	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:46122-736-04	3 in 1 CARTON	07/20/2023	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA209339		07/19/2023	

**Labeler** - Amerisource Bergen (007914906)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(46122-736) , MANUFACTURE(46122-736)

Revised: 3/2024

Amerisource Bergen