

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

**CVS Pharmacy, Inc.**

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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

#### **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 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: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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

**CVSHealth™**

**Treats Frequent Heartburn**

**May take 1 to 4 days for full effect 24 HOUR**

**Esomeprazole Magnesium**

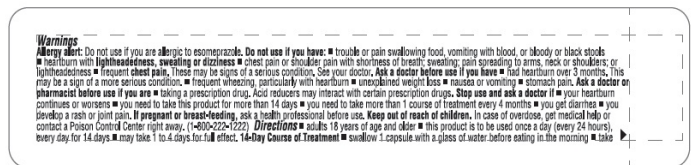
**DELAYED-RELEASE CAPSULES USP 20 mg\***

**Acid reducer**

**14 CAPSULES**

**One 14-day course of treatment**

Top Ply

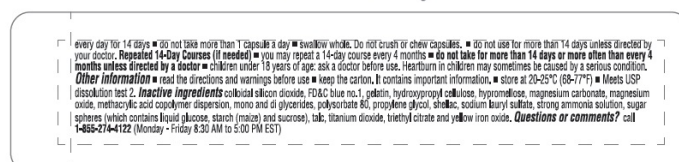


Top Ply  
(Page #1)

Back of Top Ply  
(Page #2)

Bottom Ply

Base  
(Page #3)



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

**CVSHealth™**

**Compare to the active  
ingredient in Nexium® 24 HR\*\***

**Treats Frequent Heartburn**

**May take 1 to 4 days for full effect                      24 HOUR**

**Esomeprazole Magnesium**

**DELAYED-RELEASE**

**CAPSULES USP 20 mg\***

**Acid reducer**

**See new warning information**

**14 CAPSULES**

**One 14-day Course  
of treatment**

**Actual Size**



**Compare to the active**

**ingredient in Nexium® 24 HR\*\***

**Treats Frequent Heartburn**

**May take 1 to 4 days for full effect**

**24 HOUR**

**Esomeprazole Magnesium**

**DELAYED-RELEASE**

**CAPSULES USP 20 mg\***

**Acid Reducer**

**See new warning information**

**28 CAPSULES**

**(2 bottles of 14 each)**

**Two 14-day courses of treatment**

**Actual Size**



**May take 1 to 4 days for full effect      24 HOUR**

**Esomeprazole Magnesium  
DELAYED-RELEASE  
CAPSULES USP 20 mg\***

**Acid reducer  
See new warning information**

**42 CAPSULES  
(3 bottles of 14 each)  
Three 14-day courses of treatment      Actual Size**





ESOMEPRAZOLE MAGNESIUM			
esomeprazole magnesium capsule, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-248
Route of Administration	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:69842-248-06	1 in 1 CARTON	07/09/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-248-08	2 in 1 CARTON	07/09/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination		

2		Product		
3	NDC:69842-248-10	3 in 1 CARTON	07/09/2019	
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	ANDA209339	07/09/2019	

**Labeler -** CVS Pharmacy, Inc. (062312574)

**Registrant -** Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(69842-248) , MANUFACTURE(69842-248)

Revised: 3/2021

CVS Pharmacy, Inc.