

**ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release**  
**Aurohealth LLC**

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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:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

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

**AUROHEALTH**

**NDC 58602-809-05**

**Esomeprazole Magnesium**

**Delayed-Release**

**Capsules USP 20 mg\***

**Acid Reducer**

**24 HR**

May take 1 to 4 days

for full effect

**Treats Frequent Heartburn**

**14 Capsules**

**One 14-day course of treatment**

# Top Ply

 NDC 58602-809-05	<b>Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.</b> <b>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.</b> Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India Code: TS/DRUGS/22/2009	<b>Active ingredient (in each capsule)</b> *Esomeprazole 20 mg (Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate USP) <b>Uses</b> = 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	<b>Purpose</b> Acid reducer P1431523 Lift Here
<b>Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg*</b> Treats Frequent Heartburn May take 1 to 4 days for full effect			
<b>Acid Reducer</b> 24 HR	<b>14 Capsules</b> One 14-day course of treatment	<b>Capsules</b>	<b>No Varnish</b>

## Top Ply (Page #1)

**Warnings** P1431523

**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

## Back of Top Ply (Page #2)

# Bottom Ply

## Base (Page #3)

= 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)

P1431523

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Carton)

#Compare to Nexium® 24 HR

Active ingredient

**AUROHEALTH**

**NDC 58602-809-05**

**See new warning information**

**Esomeprazole Magnesium  
Delayed-Release  
Capsules USP  
20 mg\*  
Acid Reducer  
24 HR  
Treats Frequent Heartburn**

May take 1 to 4 days for full effect  
**14 Capsules**  
**One 14-day Course of treatment**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (28 Capsule Container Carton)**

**AUROHEALTH**  
**NDC 58602-809-61**  
**#Compare to Nexium® 24 HR Active ingredient**

**See new warning information**  
**Esomeprazole Magnesium**  
**Delayed-Release Capsules USP**  
**20 mg\***  
**Acid Reducer**  
**24 HR**  
**Treats Frequent Heartburn**  
 May take 1 to 4 days for full effect  
**28 Capsules**  
**(2 bottles of 14 each)**  
**Two 14-day courses of treatment**



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

**AUROHEALTH**  
**NDC 58602-809-05**  
 #Compare to Nexium® 24 HR Active ingredient  
**See new warning information**  
**Esomeprazole Magnesium**  
**Delayed-Release**  
**Capsules USP**  
**20 mg\***  
**Acid Reducer**  
**24 HR**  
**Treats Frequent Heartburn**  
 May take 1 to 4 days for full effect

# 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:58602-809
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESOMEPRAZOLE MAGNESIUM DIHYDRATE (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:58602-809-05	1 in 1 CARTON	10/16/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-809-61	2 in 1 CARTON	10/16/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-809-62	3 in 1 CARTON	10/16/2017	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA209339	10/16/2017	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-809) , MANUFACTURE(58602-809)

Revised: 4/2024

Aurohealth LLC