

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

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**Esomeprazole Magnesium Delayed-Release Tablets 20 mg\***

***Drug Facts***

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

\*Esomeprazole 20 mg  
(Each film-coated delayed-release tablet 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 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***

colloidal silicon dioxide, crospovidone, hydroxy propyl cellulose, hypromellose, low substituted hydroxy propyl cellulose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion (which contains copolymer based on ethyl acrylate and methacrylic acid, polysorbate 80 and sodium lauryl sulfate), microcrystalline cellulose, mono and di-glycerides, polyethylene glycol, polysorbate 80, red iron oxide, sodium stearyl fumarate, 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)

### **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.

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 Tablets)**

**AUROHEALTH**

**NDC 58602-840-05**

**Esomeprazole Magnesium  
Delayed-Release Tablets 20 mg\***

**Acid Reducer  
24 HR**

May take 1 to 4 days for full effect

**Treats Frequent Heartburn  
14 Tablets**

# One 14-day course of treatment

 <p>NDC 58602-840-05</p> <p><b>Esomeprazole Magnesium Delayed-Release Tablets 20 mg*</b></p> <p><b>Acid Reducer</b></p> <p><b>24 HR</b></p>	<p>Do not use if seal imprinted with <b>SEALED for YOUR PROTECTION</b> under the bottle cap is broken or missing.</p> <p><b>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.</b></p> <p>Distributed by: <b>AUROHEALTH LLC</b> 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India Code: TS/DRUGS/22/2009</p>	<p><b>Active ingredient (in each tablet)</b> *Esomeprazole 20 mg (Each film-coated delayed-release tablet corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)</p> <p><b>Purpose</b> Acid reducer</p> <p><b>Uses</b> ■ treats frequent heartburn (occurs <b>2 or more</b> days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p>	<p>P1424827</p> <p>Lift Here</p>
	<p>May take 1 to 4 days for full effect Treats Frequent Heartburn</p> <p><b>14 Tablets</b> One 14-day course of treatment</p>	<p>* Lot: XXXXXXXXX EXP: MM/YYYY Prefix &amp; Variables of Lot, EXP shall be printed online during packing.</p>	<p>No Varnish</p>

## Top Ply (Page #1)

\* Lot: XXXXXXXXX  
EXP: MM/YYYY  
Prefix & Variables of Lot, EXP shall be printed online during packing.

<p><b>Warnings</b></p> <p><b>Allergy alert:</b> ■ 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. <b>Do not use if you have:</b> ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with <b>lightheadedness, sweating or dizziness</b> ■ 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. <b>Ask a doctor before use if you have</b> ■ 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. <b>Ask a doctor or pharmacist before use if you are</b> ■ taking a prescription drug. Acid reducers may interact with certain prescription drugs. <b>Stop use and ask a doctor if</b> ■ 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</p>	<p>P1424827</p>
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## Back of Top Ply (Page #2)

## Bottom Ply

## Base (Page #3)

<p>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. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) <b>Directions</b> ■ 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. <b>14-Day Course of Treatment</b> ■ 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 <b>Repeated 14-Day Courses (if needed)</b> ■ 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. <b>Other information</b> ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20° to 25°C (68° to 77°F) <b>Questions or comments?</b> call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)</p>	<p>P1424827</p>
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# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Tablets)

#Compare to Nexium® 24 HR  
Active ingredient

**AUROHEALTH**

**NDC 58602-840-05**  
See new warning information

**Esomeprazole Magnesium  
Delayed-Release  
Tablets 20 mg\***

**Acid Reducer  
24 HR**

**Treats Frequent Heartburn**

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

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

**Drug Facts (continued)**

**Ask a doctor before use if you have**

- had heartburn over 2 months. This may be a sign of a more serious condition.
- requent wheezing, particularly with heartburn
- unexplained weight loss
- trouble 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 for advice.**

**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 16 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

1 Bottle Inside



**Esomeprazole Magnesium  
Delayed-Release Tablets 20 mg\***  
Acid Reducer  
24 HR  
One 14-day course of treatment

**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
- chewable white. Do not crush or chew tablets.
- do not use for more than 14 days unless directed by your doctor
- do not use for more than 14 days unless directed by your doctor
- 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 16 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 this carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

**Inactive ingredients:** central silicon dioxide, croscopolamide, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium carbonate, magnesium oxide, methacrylic acid and methyl acrylate copolymer dispersion (which contains copolymer based on allyl acrylate and methacrylic acid, polyisobutyl acrylate and sodium lauryl sulfate), microcrystalline cellulose, mono and di-glycerols, polyethylene glycol.

#Compare to Nexium® 24 HR  
Active ingredient

**NDC 58602-840-05**

See new warning information  
**Esomeprazole Magnesium  
Delayed-Release  
Tablets 20 mg\***  
**Acid Reducer**  
24 HR

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

**Drug Facts (continued)**

polystyrene 80, red iron oxide, sodium stearyl fumarate, sugar spheres (which contain lactulose, titanium dioxide and carboxymethylcellulose), titanium dioxide, triethyl citrate and yellow iron oxide.

**Questions or comments?** call 1-866-274-4122 (Monday - Friday 9:00 AM to 5:00 PM EST)

Lot: \_\_\_\_\_  
Expiry: \_\_\_\_\_

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**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.

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

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Nexium® 24 HR

Distributed by: AUROHEALTH LLC  
278 Princeton-Hightstown Road  
East Windsor, NJ 08520  
Made in India  
Code: TS/GRUSS/22/2009

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Esomeprazole 20 mg	Acid reducer
Each film-coated delayed-release tablet corresponds to 21.75 mg esomeprazole magnesium trihydrate USP.	

**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**

Always read:

- Do not use if you are allergic to esomeprazole.
- Esomeprazole may cause severe skin reactions.

Symptoms may include:

- skin redness
- blister
- itch

If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use if you have:**

- history of pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with light-headedness, swelling or dizziness
- ached pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- recent chest pain.

These may be signs of a serious condition. See your doctor.

**ESOMEPRAZOLE MAGNESIUM**  
esomeprazole magnesium tablet, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-840
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE (120 .MU.M)</b> (UNII: 68401960MK)	
<b>HYDROXYPROPYL CELLULOSE (20000 WAMW)</b> (UNII: KZQ570MOA5)	
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (11% HYDROXYPROPYL; 130000 MW)</b> (UNII: 7773C1ROEU)	
<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>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>MICROCRYSTALLINE CELLULOSE 301</b> (UNII: W7YXH6D4BD)	
<b>MICROCRYSTALLINE CELLULOSE 302</b> (UNII: 91B875MM4H)	
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98RO82HJ)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<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>	PINK (Light pink)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong, Biconvex)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	K;12
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-840-05	1 in 1 CARTON	07/12/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-840-61	2 in 1 CARTON	07/12/2023	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-840-62	3 in 1 CARTON	07/12/2023	
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	ANDA214473	07/12/2023	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-840) , MANUFACTURE(58602-840)

Revised: 7/2023

Aurohealth LLC