ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium tablet, delayed release
Aurohealth LLC

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

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 Tablets
One 14-day course of treatment

Top Ply

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Treats Frequent Heartburn

24 HR

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

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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279 Princeton-Hightstown Road
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Active ingredient (in each tablet) ***Purpose***
*Esomeprazole 20 mg ..... Acid reducer
(Each film-coated delayed-release tablet corresponds to 21.75 mg esomeprazole magnesium dihydrate 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

Lift Here

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*

Unvarnished Zone
(dotted line not for printing)
27 x 13 mm

Top Ply (Page #1)

*Lot: XXXXXXXXX
Exp.: YYYY-MMM
Prefix, Variables of Lot, Exp and Neutral code shall be printed online during packing.

P1437857

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

Back of Top Ply (Page #2)

Bottom Ply

Base (Page #3)

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

P1437857

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (42 Tablets)

#Compare to Nexium® 24 HR Active ingredient

AUROHEALTH

NDC 58602-840-62
See new warning information

Esomeprazole Magnesium
Delayed-Release
Tablets 20 mg*

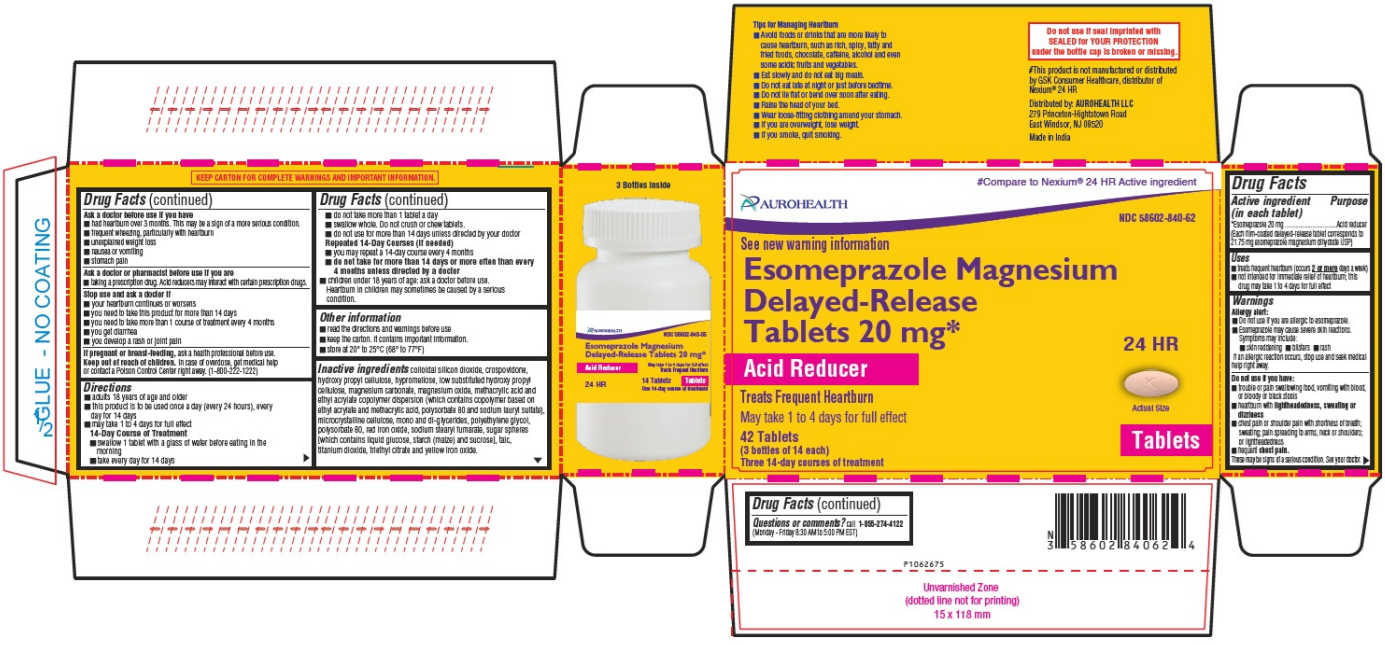
Acid Reducer
24 HR

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

Actual Size
Tablets

42 Tablets

(3 bottles of 14 each)
Three 14-day courses of treatment



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-840
Route of Administration	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYDROXYPROPYL CELLULOSE (20000 WAMW) (UNII: KZQ570MOA5)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (11% HYDROXYPROPYL; 130000 MW) (UNII: 7773C1ROEU)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MICROCRYSTALLINE CELLULOSE 301 (UNII: W7YXH6D4BD)	
MICROCRYSTALLINE CELLULOSE 302 (UNII: 91B875MM4H)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK (Light pink)	**Score**	no score
Shape	OVAL (Oblong, Biconvex)	**Size**	13mm
Flavor		**Imprint Code**	K;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	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: 2/2026 Aurohealth LLC