

ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium tablet, delayed release

Cardinal Health

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
CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6313

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Tablets Bottle)

LEADER™

NDC 70000-0695-1
24 Hour

Esomeprazole
Magnesium
Delayed-Release Tablets, 20 mg* | Acid Reducer

Treats Frequent Heartburn

14 TABLETS

One 14-Day Course of Treatment (May take 1 to 4 days for full effect)

Top Ply

NDC 70000-0695-1 24 Hour Esomeprazole Magnesium Delayed-Release Tablets, 20mg* Acid Reducer	LEADER²	Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.	Active ingredient (in each tablet) *Esomeprazole 20 mg Acid reducer (Each film-coated delayed-release tablet corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)	Purpose P1434608 LM-5870
		KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.	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 ▼
Treats Frequent Heartburn 14 TABLETS One 14-Day Course of Treatment (May take 1 to 4 days for full effect)	DIST. BY CAH DUBLIN, OH 43017 www.myleader.com 1-800-200-6313 ©2024 Cardinal Health. CIN 5915038 Made in India REV. 04/24	100% Money Back Guarantee Return to place of purchase if not satisfied.	Unvarnished Zone (dotted line not for printing) 27 x 13 mm	

Top Ply (Page #1)

Warnings P1434608 LM-5870

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**

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Bottom Ply

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)

P1434608 LM-5870

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

LEADER™

**NDC 70000-0695-1
24 Hour**

**Esomeprazole
Magnesium
Delayed-Release Tablets, 20 mg*
Acid Reducer**

**COMPARE TO
NEXIUM® 24 HR
active ingredient****

**100 % Money
Back Guarantee**

Treats Frequent
Heartburn

May Take 1 to 4 Days
for Full Effect

**14 TABLETS
One 14-Day Course
of Treatment**

Actual Size

SEE NEW WARNING INFORMATION



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0695
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)	
CROSPROVIDONE (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 Date	Marketing End Date
1	NDC:70000-0695-1	1 in 1 CARTON	06/27/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0695-2	3 in 1 CARTON	06/27/2024	
2		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	06/27/2024	
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Labeler - Cardinal Health (063997360)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(70000-0695) , MANUFACTURE(70000-0695)

Revised: 6/2024

Cardinal Health