

ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release

Graviti Pharmaceuticals Private Limited

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg

Esomeprazole Magnesium Drug Facts

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.250 mg esomeprazole magnesium trihydrate)

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.

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 Repeated 14-Day Courses (if needed)

- 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
- 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).

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg:

FD&C Blue 2, Gelatin, Hydroxypropyl Cellulose, Hypromellose, Magnesium Stearate, Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, Mono- and Di-Glycerides, Pharmaceutical Ink, Polysorbate 80, Sugar Spheres, Talc, Triethyl Citrate.

Questions or comments?

Call Toll-free weekdays 9AM to 5PM EST at **1-855-298-4506**

Contact Graviti Pharmaceuticals Inc., or www.gravitipharma.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Made in India

Additional Information

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or Blue band around the center of each capsule is broken or missing.

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.

Marketed by:

Graviti Pharmaceuticals Inc.,
Wilmington, Delaware-19801,
USA.

Made in India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Principal Display Panel - 20 mg Capsules: Container Label

NDC 69844-050-01

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg

Acid Reducer

Treats Frequent Heartburn

May take 1 to 4 Days for Full effect

24 HR

14 Capsules

One 14-day Course of Treatment

See New Warning Information

Manufactured for Graviti Pharmaceuticals Inc.

Made in India.

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14 Capsules
One 14-day course of treatment

graviti
pharma

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

NVZ
33 x 14 mm

Active ingredient (in each capsule)
Esomeprazole 20 mg
(Each delayed-release capsule corresponds to 22.250 mg esomeprazole magnesium trihydrate)

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 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.

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° to 25°C (68° to 77°F).

Questions or comments? Call toll-free weekdays 9 AM to 5 PM EST at 1-855-298-4506

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Principal Display Panel - 14 Capsule Carton label

NDC 69844-050-01

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg

Acid Reducer

Treats Frequent Heartburn

May take 1 to 4 Days for Full effect

24 HR

14 Capsules

One 14-day Course of Treatment

See New Warning Information

Manufactured for Graviti Pharmaceuticals Inc.

Made in India.



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69844-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESOMEPRAZOLE MAGNESIUM (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR (UNII: 8M707QY5GH)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERYL DISTEARATE (UNII: 73071MW2KM)	

Product Characteristics

Color	WHITE (white opaque colored)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	20mg;223
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69844-050-01	1 in 1 CARTON	06/24/2022	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69844-050-02	2 in 1 CARTON	06/24/2022	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69844-050-03	3 in 1 CARTON	06/24/2022	
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	ANDA216349	06/24/2022	

Labeler - Graviti Pharmaceuticals Private Limited (650884781)

Registrant - Graviti Pharmaceuticals Private Limited (650884781)

Establishment

Name	Address	ID/FEI	Business Operations
Graviti Pharmaceuticals Private Limited		650884781	MANUFACTURE(69844-050) , ANALYSIS(69844-050)

Revised: 11/2022

Graviti Pharmaceuticals Private Limited