BASIC CARE ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release L. Perrigo Company

Amazon Esomeprazole Magnesium Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22 mg esomeprazole magnesium dihydrate)

Purpose

Acid reducer

Uses

- treats frequent heartburn (occurs <u>2 or more</u> 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

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)

Inactive ingredients

FD&C blue no. 1, FD&C red no. 3, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Nexium® 24 HR active ingredient

Capsules

esomeprazole magnesium delayed-release capsules, 20 mg / Acid Reducer

Treats Frequent Heartburn

24 HR

actual size

May take 1 to 4 days for full effect

See new warning information

42 CAPSULES

three 14-day courses of treatment



Clinically Proven to Treat Frequent Heartburn

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts

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Warnings

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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
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Ask a doctor before use if you have

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- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
 stomach pain

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■ 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

Drug Facts (continued)

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

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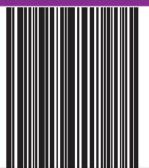
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Inactive ingredients

FD&C blue no. 1, FD&C red no. 3, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid and ethyl acrylate copolymer dispersion polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260



esomeprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0732
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ESOMEPRAZOLE (UNII: N3PA6559FT) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
GELATIN (UNII: 2G86QN327L)		
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MEGLUMINE (UNII: 6 HG8 UB2MUY)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
SHELLAC (UNII: 46 N10 7B71O)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics			
Color	BLUE (opaque)	Score	no score
Shape	CAPSULE (oblong)	Size	14mm
Flavor		Imprint Code	L898
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0113-0732-01	1 in 1 CARTON	0 1/0 9 /20 18	
1	14 in 1 BOTTLE; Type 0: Not a Combination Product		
2 NDC:0113-0732-03	3 in 1 CARTON	0 1/0 9 /20 18	
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	ANDA207193	01/09/2018	

Labeler - L. Perrigo Company (006013346)

Revised: 10/2019 L. Perrigo Company