

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release RUGBY LABORATORIES

Drug Facts

Active ingredient(s) in each capsule

*Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, 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

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 lightheadness
- 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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- diazepam (anxiety medicine)
- tacrolimus or mycophenolate mofetil (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask 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

- each capsule contains: magnesium, 15 mg
- read directions and warnings before use
- keep the carton. It contains important information
- store at 20 to 25°C (68 to 77°F)

Inactive ingredients

acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, poloxamer, polysorbate 80, povidone, potassium hydroxide, propylene glycol, shellac, sugar, talc, titanium dioxide

Questions or comments

call toll-free weekdays 8 AM to 10 PM EST at 1-888-375-3784

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.

Bottle Label

Container Label:


NDC 0536-1230-88

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg*
Acid Reducer

24
HOUR

Treats Frequent Heartburn

May take 1 to 4 days for full effect

One 14-Day Course of Treatment
14 Capsules

TAMPER EVIDENT FEATURES: Do not use if foil seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or black band around the center of each capsule is broken or missing.

KEEP THE CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts

Active ingredient Purpose (in each capsule)
 Esomeprazole 20 mg.....Acid reducer
 (Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, 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
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

Distributed by: Rugby Laboratories
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152
 Rev. 05/19 R-145 Re-order No. 370708
Made in India
 LOT/EXP 150076259

PEEL HERE 

Reseal Area

Drug Facts (continued)

- 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 the arthrum ■ 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)

Hinge

Hinge

Drug Facts (continued)

Directions

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Inactive ingredients
 acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, poloxamer, polysorbate 80, povidone, potassium hydroxide, propylene glycol, stearic acid, sugar, talc, titanium dioxide

Questions or comments? call toll-free weekdays 8 AM to 10 PM EST at 1-888-375-3784

Hinge

Carton

Carton

No Coating Area

LSZ970051

Compare to the active ingredient in Nexium® 24HR

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg*
Acid Reducer

No Coating Area

150076257

Compare to the active ingredient in Nexium® 24HR

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg*
Acid Reducer

Treats Frequent Heartburn

May take 1 to 4 days for full effect

14 Capsules
One 14-Day Course of Treatment

Actual Size

1 BOTTLE INSIDE

Rev. 05/19 R-145 Re-order No. 370706

3 05361 23088 3

ESOMEPRAZOLE MAGNESIUM			
esomeprazole magnesium capsule, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1230(NDC:43598-407)
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
acetyltributyl citrate (UNII: 0ZBX0N59RZ)			
Dibutyl Sebacate (UNII: 4W5IH7FLNY)			
Ferrosulfate Oxide (UNII: XM0M87F357)			
Gelatin (UNII: 2G86QN327L)			
Glyceryl Monostearate (UNII: 230OU9XXE4)			
Hypromelloses (UNII: 3NXW29V3WO)			
Magnesium Oxide (UNII: 3A3U0GI7IG)			
Magnesium Stearate (UNII: 70097M6I30)			
Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A (UNII: NX76LV5T8J)			
Poloxamer 188 (UNII: LQA7B6G8JG)			
Polysorbate 80 (UNII: 6OZP39ZG8H)			
Povidone K30 (UNII: U725QWY32X)			
Talc (UNII: 7SEV7J4R1U)			
Titanium Dioxide (UNII: 15FIX9V2JP)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Potassium Hydroxide (UNII: WZHBC48M4T)	
Shellac (UNII: 46N107B71O)	
Sucrose (UNII: C151H8M554)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE (light blue cap) , BLUE (dark blue body)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	RDY;327
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1230-88	1 in 1 CARTON	05/28/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0536-1230-13	3 in 1 CARTON	05/28/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0536-1230-71	2 in 1 CARTON	05/28/2019	
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	ANDA207673	05/28/2019	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 5/2019

RUGBY LABORATORIES