

ESOMEPRAZOLE- esomeprazole capsule
Reliable 1 Laboratories

Reliable-1 Esomeprazole Magnesium DR Capsules

Drug Facts

Active ingredient (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 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

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

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

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 the directions and warnings before use
 keep the carton. It contains important information.
 store at 20-25°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**

NDC 69618-056-42

Compare to the active ingredient in Nexium® 24 HR**

Esomeprazole Magnesium

Delayed-Release Capsules, USP

20 mg*

Acid Reducer

42 Capsules

Three 14-day Courses of Treatment



ESOMEPRAZOLE

esomeprazole capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-056
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
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
DIBUTYL SEBACATE (UNII: 4W5IH7FLNY)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow (Gelatin capsule shell with light blue cap and dark blue body)	Score	no score
Shape	OVAL (Capsule)	Size	9mm
Flavor		Imprint Code	RDY;327
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69618-056-42	3 in 1 CARTON	11/01/2018	
1	NDC:69618-056-14	14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207673	11/01/2018	

Labeler - Reliable 1 Laboratories (079718111)

Revised: 8/2021

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