

ACID REDUCER- esomeprazole magnesium capsule, delayed release
P & L Development, LLC

Esomeprazole Magnesium Delayed-Release Capsules 20 mg - Actavis

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

(*Each delayed-release capsule corresponds to 22.25 mg esomeprazole magnesium, USP 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

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

- 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 (1-800-222-1222) 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)

Inactive ingredients

black iron oxide, colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium stearate, methacrylic acid - ethyl acrylate copolymer dispersion, microcrystalline cellulose, mono- and di-glycerides, polyethylene glycol, polysorbate 80, propylene glycol, red iron oxide, shellac glaze, sodium lauryl sulfate, sodium stearyl fumarate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Nexium® 24R†

see new warning information

24-hour

esomeprazole magnesium

delayed-release capsules

USP, 20 mg*

acid reducer

treats frequent heartburn

may take 1 to 4 days for full effect

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Nexium® 24HR.

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP BROKEN OR MISSING. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package label

Drug Facts Active ingredient (in each tablet) Esomeprazole 20 mg* Acid reducer (*Each delayed-release tablet corresponds to 22.25 mg esomeprazole magnesium, USP (rhydrate)) 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 a prescription drug. Acid reducers may interact with certain prescription drugs.	Drug Facts (continued) 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 (1-800-222-1222) 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 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.	Drug Facts (continued) 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 black iron oxide, colloidal silicon dioxide, croscopolone, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer dispersion, microcrystalline cellulose, mono- and di-glycerides, polyethylene glycol, polyorbate 80, polyethylene glycol, red iron oxide, shelic glass, sodium lauryl sulfate, sodium steryl fumarate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST *This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Nexium® 24HR. TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING. KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.	 see new warning information Compare to the active ingredient in Nexium® 24HR† NDC 59726-056-14 24-hour esomeprazole magnesium delayed-release tablets, 20 mg* acid reducer actual size 14 tablets (1 bottle inside) one 14-day course of treatment Distributed by: PL Developments 200 Hicks Street Westbury, NY 11590 Code No.: MH/DRUGS25/NKD/89 PLD-4722A FC007474 Lot No.: Exp. Date: 3 59726 56014 6	see new warning information 24-hour esomeprazole magnesium delayed-release tablets, 20 mg* acid reducer 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.
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READYinCASE Acid Reducer

ACID REDUCER

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-056
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
GLYCERYL MONO AND DIPALMITO STEARATE (UNII: KC98RO82HJ)	
MAGNESIUM STEARATE (UNII: 70097M6B0)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
CROSPVIDONE (UNII: 2S7830E561)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	EL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-056-14	1 in 1 CARTON	12/31/2020	
1		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	ANDA212088	12/31/2020	

Labeler - P & L Development, LLC (800014821)

Revised: 1/2021

P & L Development, LLC