ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release Kroger Company

Kroger Co. 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 blue no. 1 aluminum lake, 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?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredient of NEXIUM® 24HR CLEAR MINIS™

See side panel

Kroger_®

Esomeprazole Magnesium

OUR PHARMACIST RECOMMENDED

Treats Frequent Heartburn

24 HR

Mini Capsules

Delayed-Release Capsules, 20 mg

ACID REDUCER

actual size

42 CAPSULES

See New Warning Information

Three 14-Day Courses of Treatment

May Take 1 to 4 Days for Full Effect



Delayed-Release Capsules, 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.

Clinically Proven to Treat Frequent Heartburn

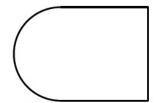
Treats Frequent Heartburn

24 HR 🖰

COMPARE TO the active ingredient of NEXIUM® 24HR CLEAR MINIS™ *See side panel













Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg **ACID REDUCER**

See New Warning Information



Treats Frequent Heartburn

24 HR (5)

Mini Capsules



42 CAPSULES

Three 14-Day Courses of Treatment May Take 1 to 4 Days for Full Effect



NDC 30142-273-01

Esome prazole Magnesium

Frequent Heartburn 24 HR 🖰

Delayed-Release Capsules, 20 mg ACID REDUCER

Mini Capsules 14 CAPSULES

One 14-Day Course of Treatment May Take 1 to 4 Days for Full Effect

actual size

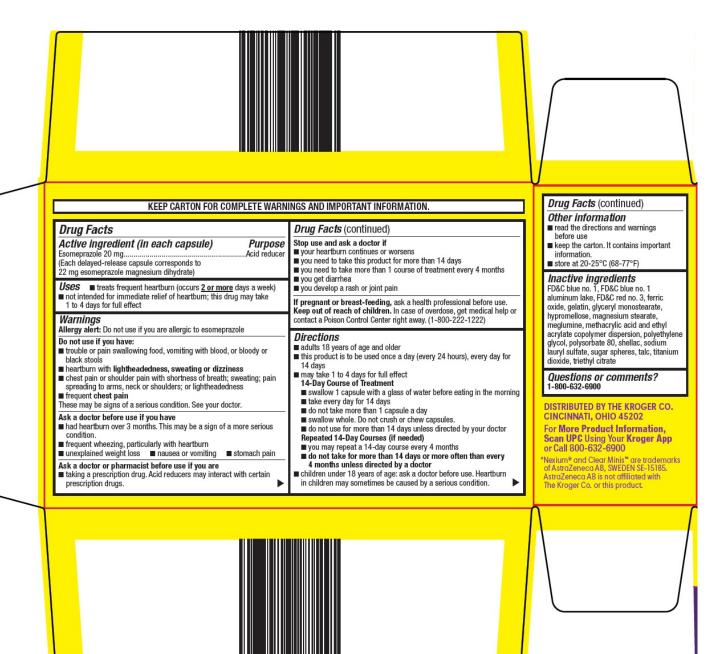
DO NOT USE IF PRINTED FOIL SEAL UNDER CAP OR BAND A ROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING.





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7U4D7 45 C1



ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-273
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SHELLAC (UNII: 46N107B710)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	7U4	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30142-273- 01	1 in 1 CARTON	05/13/2022		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:30142-273- 03	3 in 1 CARTON	05/25/2022		
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	05/13/2022		

Labeler - Kroger Company (006999528)

Revised: 10/2023 Kroger Company