ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release
Allegiant Health

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017 - ESOMEPRAZOLE MAGNESIUM capsule, delayed release

Active ingredient(s)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.250 mg esomeprazole magnesium trihydrate)

Purpose

Acid reducer

Use(s)

- 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 effe

Warnings

- Do not use if you are allergic to esomeprazole.
- Esomeprazole may cause severe skin reactions. Symptoms may include:
- Skin reddening
- Blisters
- Rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- 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

- 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 breastfeeding,

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 Repeated 14-Day Courses (if needed)

- 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
- 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

FD&C Blue 2, Gelatin, Hydroxypropyl Cellulose, Hypromellose, Magnesium Stearate, Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, Mono-and Di-Glycerides, Pharmaceutical Ink, Polysorbate 80, Sugar Spheres, Talc, Triethyl Citrate.

Questions/Comments

Call 1-888-952-0050 Monday through Friday 9AM – 5PM EST

Principal Display Panel

Active ingredient (in each capsule) ***Purpose***

Esomeprazole 20 mg .....Acid reducer

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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

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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 ■ frequent **chest pain.** These may be signs of a serious condition. See your doctor.

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Esomeprazole 20 mg Label 42ct

Esomeprazole 20 mg Carton 42ct

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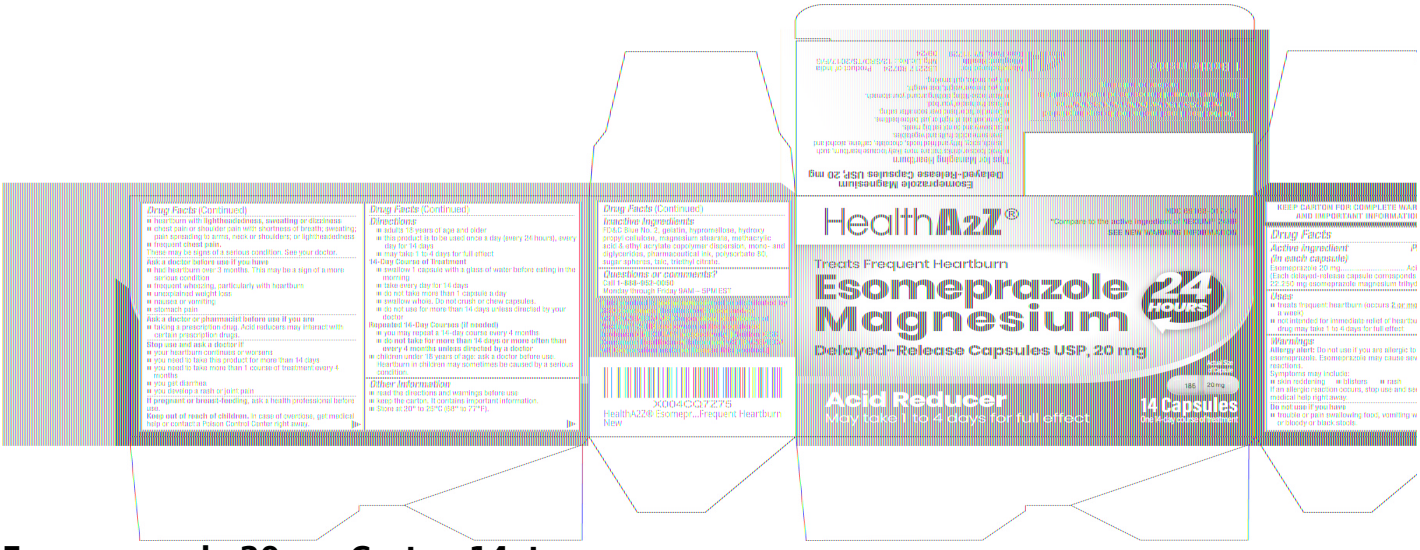
Esomeprazole 20 mg Label 14ct



Esomeprazole 20 mg Carton 14ct

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-017
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERYL DISTEARATE (UNII: 73071MW2KM)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
RAW SUGAR (UNII: 8M707QY5GH)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	white	**Score**	no score

Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	186;20mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-017-14	1 in 1 CARTON	10/29/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-017-42	3 in 1 CARTON	10/29/2024	
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	ANDA216349	10/29/2024	

Labeler - Allegiant Health (079501930)

Revised: 10/2024 Allegiant Health