

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release capsule
Allegiant Health

472 - Esomeprazole Magnesium 20mg

Active ingredient(s)

Esomeprazole 20 mg

(*Each delayed-release capsule corresponds to 22.25 mg esomeprazole magnesium trihydrate USP).

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 effect.

Warnings

Allergy alert: 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

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 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 (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 20-25°C (68-77°F)

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.

Inactive ingredients

Black iron oxide, FD&C Blue No. 1, FD&C Blue No. 2, gelatin, glyceryl monostearate, hydroxy propyl cellulose, hypromellose, magnesium stearate, methacrylic acid ethyl acrylate copolymer, potassium hydroxide, polysorbate 80, propylene glycol, shellac, simethicone, sodium lauryl sulfate, strong ammonia solution, sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

Questions/Comments

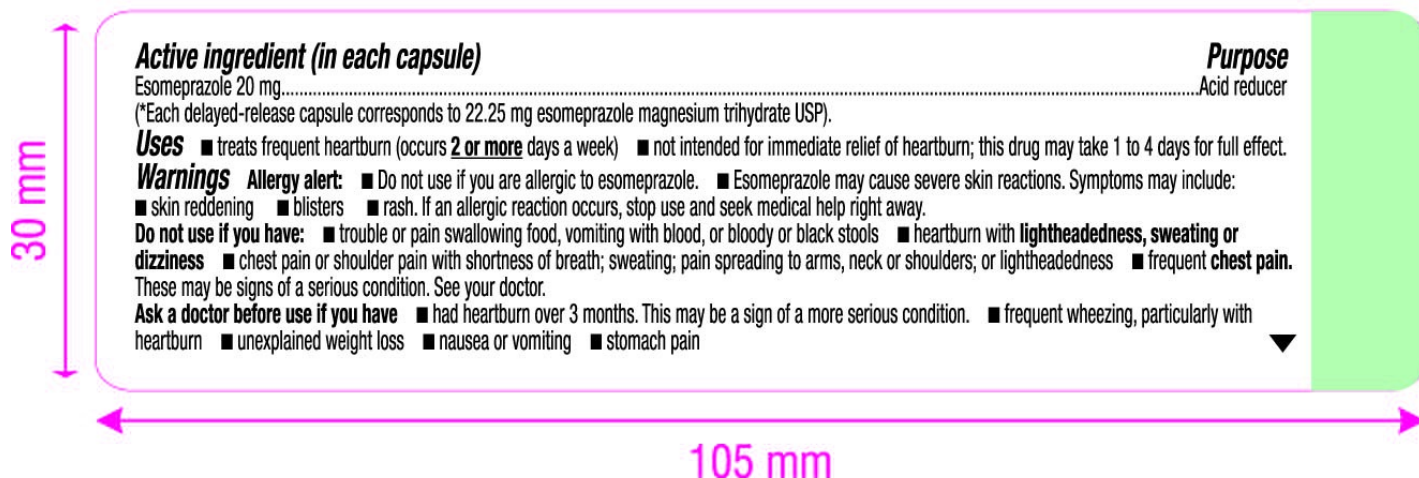
Call 1-888-952-0050 Monday through Friday
9AM - 5PM EST

Principal Display Panel

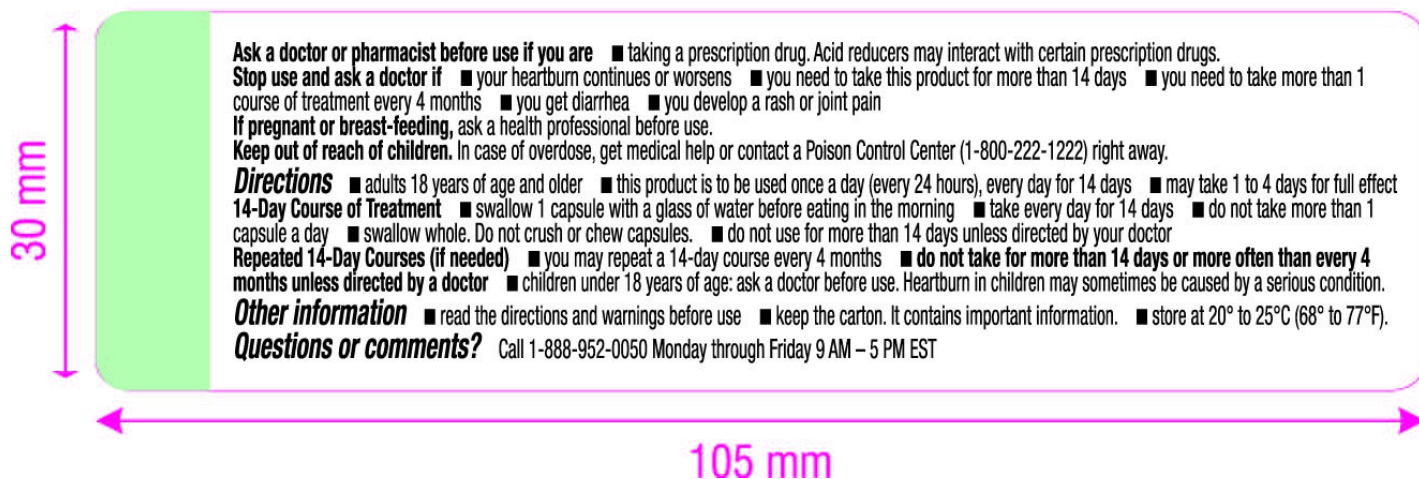
Top Layer



Top Layer Back



Second Layer



Esomeprazole Magnesium Label

2011



Do not use if carton is opened or if seal under cap is tampered with.
Keep out of reach of children. See important information on the back of each capsule for more information.

This product is not manufactured or distributed by Pfizer, distributor of Nexium® 24 Hr.
• If you are overweight, lose weight. • If you smoke, quit smoking.
• Wear loose-fitting clothing around your stomach.
• Raise the head of your bed.
• Do not lie flat or bend over soon after eating.
• Do not eat late at night or just before bedtime.
• Eat slowly and do not eat big meals.
• 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.

Unvarnished
Area for Batch coding

2104108

HealthA2Z®

NDC 69168-472-61
*Compare to the active ingredient in Nexium® 24HR

Treats Frequent Heartburn

**Esomeprazole
Magnesium**

Delayed-Release
Capsules USP,
20 mg*

24
HOUR

**Acid
Reducer**

May take 1 to 4 days
for full effect



14 Capsules

One 14-day course of treatment



3 69168 46414 8

KEEP CARTON FOR COMPLETE WARNINGS AND
IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each capsule) Purpose
Esomeprazole 20 mg.....Acid reducer
*Each delayed-release capsule corresponds to 22.25 mg esomeprazole magnesium trihydrate 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.
■ 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 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, ▶

Drug Facts (continued)

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.

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

Drug Facts (continued)

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, FD&C Blue No. 1, FD&C Blue No. 2, gelatin, glyceryl monostearate, hydroxy propyl cellulose, hypromellose, magnesium stearate, methacrylic acid ethyl acrylate copolymer, potassium hydroxide, polysorbate 80, propylene glycol, shellac, simethicone, sodium lauryl sulfate, strong ammonia solution, sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

Question or comments?

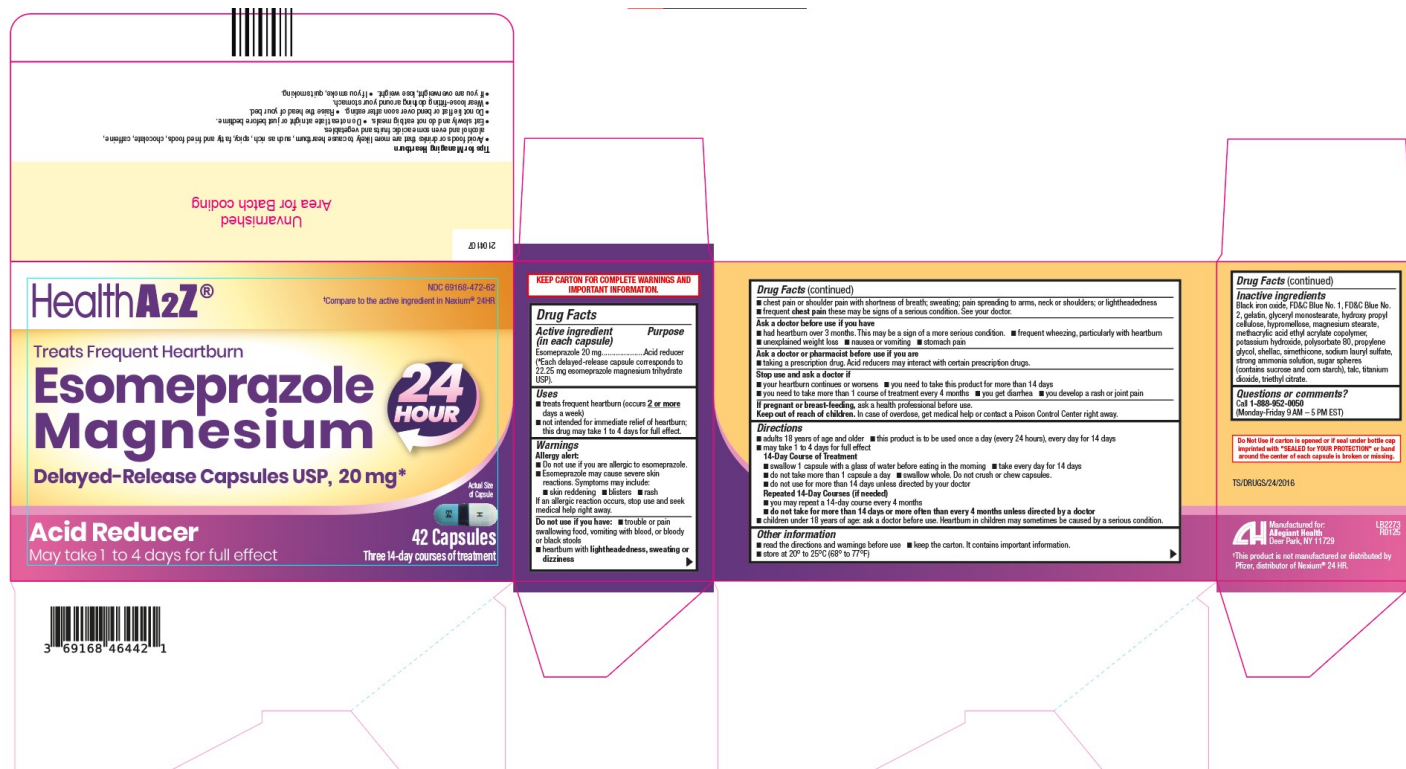
Call 1-888-952-0050
(Monday-Friday 9 AM – 5 PM EST)

15/09/15/24/0016

Manufactured for:
Allergiant Health
Dear Park, NY 11729

182251
R0134

Esomeprazole Magnesium 14ct



Esomeprazole Magnesium 42ct

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-472
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
IRON OXIDES (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
AMMONIA (UNII: 5138Q19F1X)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	blue (blue opaque body) , white (white opaque cap)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	E4;H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-472-14	1 in 1 CARTON	05/15/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-472-61	1 in 1 CARTON	05/15/2025	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-472-42	3 in 1 CARTON	05/15/2025	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69168-472-62	3 in 1 CARTON	05/15/2025	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69168-472-15	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212507	05/15/2025	

Labeler - Allegiant Health (079501930)

