

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

LEADER/ Cardinal Health 110, Inc.

Drug Facts

Active ingredient(s) in each capsule

* Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.3 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 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 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 directions and warnings before use
- keep the carton. It contains important information.
- store at 20°C to 25°C (68°F to 77°F)
- this product meets USP Dissolution Test 3

Inactive ingredients

FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, polysorbate 80, potassium hydroxide, propylene glycol, shellac, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

Questions or comments

call toll-free weekdays 8 AM to 8 PM EST at **1-888-375-3784**

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.

Distributed by

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Made in India

Principal Display Panel

Carton label, 42 count



Drug Facts

Active ingredient (in each capsule)
Esomeprazole 20 mg
Acid reducer
(Each delayed-release capsule corresponds to 22.5 mg esomeprazole magnesium trihydrate, USP)

Purpose
Acid reducer

Uses
● treats frequent heartburn (occurs 2 or more days a week)
● Esomeprazole may cause severe side reactions. Symptoms may include:
● skin redness ● hives ● rash
If an allergic reaction occurs, stop use and seek medical help right away.

Warnings
Allergy alert: ● Do not use if you are allergic to esomeprazole
● Esomeprazole may cause severe side reactions. Symptoms may include:
● skin redness ● hives ● rash
If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have:
● rashes or pain swallowing food, vomiting with blood or bloody or black stools
● heartburn with lightheadedness, swelling or dizziness
● chest pain or abdominal pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness

Take chest pain
● frequent wheezing, particularly with heartburn
● frequent weight loss ● nausea or vomiting ● stomach pain

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
● stomach 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

Drug Facts (continued)

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°C to 25°C (68°F to 77°F)
● this product meets USP Controlled Test 2

Inactive ingredients
FUSC Blue #1, ferrous lacte, oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, polyethylene glycol, potassium hydroxide, polyethylene glycol, stearic acid, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

Questions or comments?
call toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784

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.
- TAMPER EVIDENT FEATURES: Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or blank based around the center of each capsule is broken or missing.**
- KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.**
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LEADER 24 Hour Esomeprazole Magnesium
Delayed-Release Capsules USP, 20 mg* | Acid Reducer
3 BOTTLES INSIDE

LEADER 24 Hour Esomeprazole Magnesium
Delayed-Release Capsules USP, 20 mg* | Acid Reducer

Treats Frequent Heartburn
May Take 1 to 4 Days for Full Effect

42 CAPSULES
Three 14-Day Courses of Treatment

COMPARE TO NEXIUM® 24HR
active ingredient**

100% Money Back Guarantee



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LOT
EXP

Container Labeling

LEADER²

NDC 70000-0714-1
24 Hour
Esomeprazole Magnesium
 Delayed-Release Capsules
 USP, 20 mg* | Acid Reducer

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

TAMPER EVIDENT - FEATURES: Do Not Use if seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" or black band around the center of each capsule is broken or missing.

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Active ingredient (in each capsule)
 Esomeprazole 20 mg, Acid reducer (Each delayed-release capsule corresponds to 22.3 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 redness ■ 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

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 Made in India ©2024 Cardinal Health
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PEEL HERE

Reseal Area

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)

DUBLIN

Pinches

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
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Repeated 14-Day Courses (if needed)
 ■ you may repeat a 14-day course every 4 months
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■ 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°C to 25°C (68°F to 77°F) ■ this product meets USP Dissolution Test 3

Inactive ingredients
 FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, poly sorbate 80, potassium hydroxide, propylene glycol, shellac, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

Questions or comments? call toll-free weekdays 8 AM to 8 PM EST at 1-888-375-3784

ESOMEPRAZOLE MAGNESIUM			
esomeprazole magnesium capsule, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0714(NDC:43598-327)
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
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SUCROSE (UNII: C151H8M554)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
SHELLAC (UNII: 46N107B71O)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	BLUE (light blue cap and dart blue body)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	RDY;496
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0714-1	1 in 1 CARTON	03/01/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0714-3	3 in 1 CARTON	03/01/2025	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70000-0714-2	2 in 1 CARTON	03/01/2025	
3		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	ANDA207198	03/01/2025	

Revised: 11/2024

LEADER/ Cardinal Health 110, Inc.