

**ACID REDUCER- esomeprazole magnesium tablet, delayed release
H E B**

Esomeprazole Magnesium Delayed-Release Capsules 20 mg - Actavis

Drug Facts

Active ingredient (in each tablet)

Esomeprazole 20 mg

(*Each delayed-release tablet 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 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.

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 toll free: **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Nexium® 24 HR active ingredient**

See New Warning Information

Heartburn Relief 24 Hour

Esomeprazole Magnesium

Delayed-Release Tablets, 20 mg*

Acid Reducer

- Treats Frequent Heartburn
- May Take 1 to 4 days for Full Effect

TABLETS

**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 PRODUCT INFORMATION.

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

Package label

Compare to Nexium® 24HR active ingredient**

NDC:37808-856-42



See New Warning Information

Heartburn Relief 24 Hour

Esomeprazole Magnesium Delayed-Release Tablets, 20 mg*

Acid Reducer

- Treats Frequent Heartburn
- May take 1 to 4 days for full effect



actual size

42 TABLETS
(THREE BOTTLES INSIDE)
THREE 14-DAY COURSES OF TREATMENT

Drug Facts

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

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■ 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
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Do not use if you have
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■ 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.

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Drug Facts (continued)

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, 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

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TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING.

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

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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SAN ANTONIO, TX 78204



Code No.: MH/DRUGS/25/NKD/89
PLD-A722A FC007934

22710 - 2112



Lot No.:
Exp. Date:

H-E-B Acid Reducer

ACID REDUCER

esomeprazole magnesium tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-856
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 DIPALMITOSTEARATE (UNII: KC98R082HJ)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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)
CROSPROVIDONE (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	pink	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:37808-856-42	3 in 1 CARTON	03/31/2022	
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:37808-856-14	1 in 1 CARTON	03/31/2022	
2		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212088	03/31/2022	

Labeler - H E B (007924756)