

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule

YYBA CORP

Esomeprazole Aurohealth

Active ingredient (in each capsule)

Esomeprazole 20 mg (Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium trihydrate USP)

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.
- 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.**
- *Note: 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.

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)
- Meets USP dissolution test 2

Inactive ingredients

colloidal silicon dioxide, FD&C blue no.1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

Questions or comments?

call **1-866-933-6337**

20 mg (14 Capsule Container Label)

TOP PLY

welmate
HEARTBURN RELIEF
ACID REDUCER **24 HOUR**
Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg*
Treats Frequent Heartburn
May take 1 to 4 days for full effect
14 CAPSULES One 14-day course of treatment
RECOMMENDED BY HEALTHCARE PROFESSIONALS

Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.
KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Distributed by
WellSpring
Airmont, NY 10952 U.S.A
866-933-6337
wellspringmeds.com
Made in India

Active ingredient (in each capsule)
*Esomeprazole 20 mgAcid reducer
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)

Purpose
P 1437848

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

Unvarnished Zone (dotted line not for printing)
12 x 27 mm

Lift Here

Top Ply

(Page #1)

Warnings **P 1437848**

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 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

Top Ply

(Page #2)

■ 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.

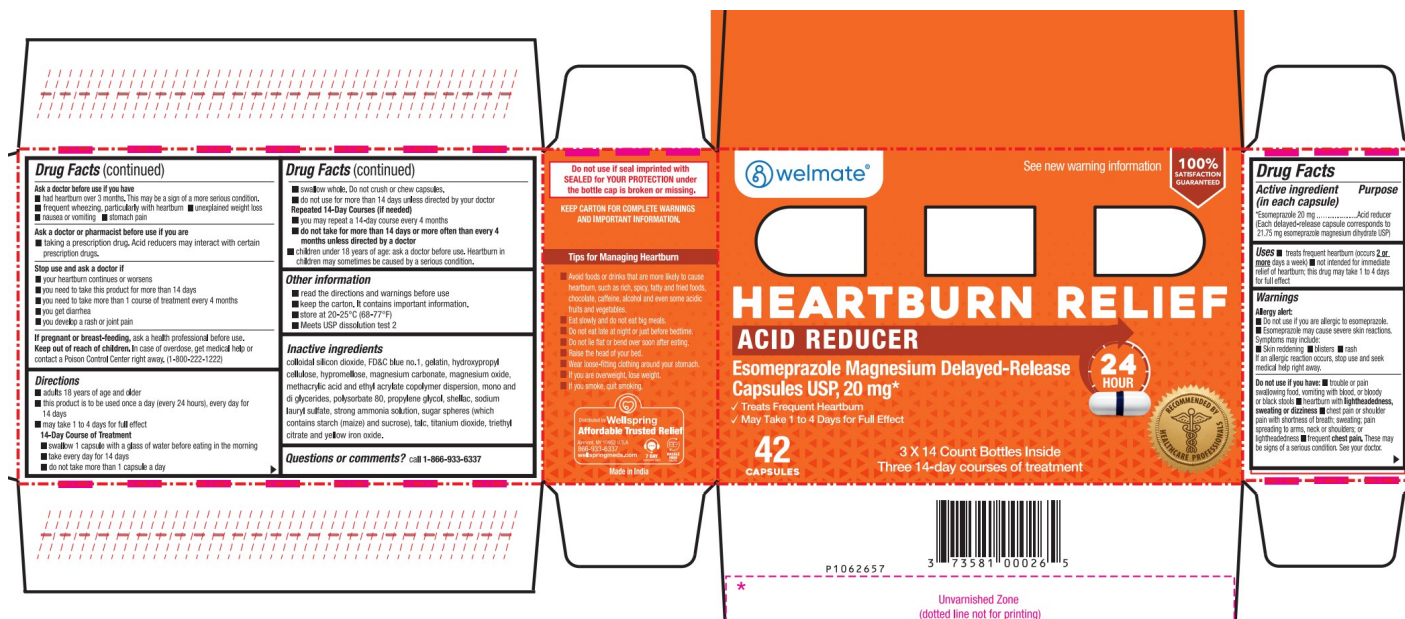
Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) ■ Meets USP dissolution test 2.

Inactive ingredients colloidal silicon dioxide, FD&C blue no.1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide. **Questions or comments?** call 1-866-933-6337

P 1437848

Base

(Page #3)



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73581-014
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
AMMONIA (UNII: 5138Q19F1X)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	I81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73581-014-42	3 in 1 CARTON	04/01/2026	
1		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	ANDA209339	04/01/2026	

Labeler - YYBA CORP (006339772)

Registrant - YYBA CORP (006339772)