

ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release

Ahold U.S.A., Inc,

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg*

Drug Facts

Active ingredient (in each capsule)

*Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate 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

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

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- diazepam (anxiety medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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
- 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 copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

Questions or comments?

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

DISTRIBUTED BY: FOODHOLD U.S.A., LLC
LANDOVER, MD 20785

Product of India
Code: TS/DRUGS/22/2009
1-877-846-9949

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Quality guaranteed or your money back.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Label)

CAREone®
NDC 60000-109-05
ESOMEPRAZOLE MAGNESIUM
Delayed-Release Capsules USP 20 mg*
Acid Reducer
24 HR
Treats Frequent Heartburn
May take 1 to 4 days for full effect
14 Capsules
One 14-day
course of treatment

Top Ply

| | | | |
|---|---|--|--|
| <p>Do not use if seal is impaired with evidence of tampering. Do not use if the bottom flap is broken or missing.</p> <p>KEEP CAPTION FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.</p> <p>DISTRIBUTED BY: PDR HOLDINGS U.S.A., LLC LANEWOOD, MD 21076 PRODUCT CODE: 1437-4462040 60200AHM14374462040 Quality guaranteed or your money back. Code: TAC000022000</p> | <p>CAREone® NDC 60000-109-05</p> <p>ESOMEPRAZOLE MAGNESIUM Delayed-Release Capsules USP 20 mg* Acid Reducer</p> <p>Treats Frequent Heartburn May take 1 to 4 days for full effect</p> <p>24hr</p> <p>One 14-day course of treatment 14 CAPSULES</p> | <p>Active Ingredient (in each capsule) Esomeprazole 20 mg Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium (Esomeprazole USP)</p> <p>Purpose Acid Reducer</p> <p>LM-3330</p> <p>No Varnish</p> | <p>Warnings</p> <p>Major 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 weight loss, weakness, or dizziness; chest pain or shoulder pain with difficulty of breath, swelling, pain spreading to arms, neck or shoulders, or light-headedness; frequent chest pain. It may be signs of a serious condition. See your doctor. Ask a doctor before use if you have: had heartburn over 3 months; this is the first of many periods of heartburn; frequent reflux, particularly with heartburn or regurgitated weight loss; frequent or chronic pain; had a fever or phlegm that worsens when you are taking warfarin, clopidogrel or clostracil (blood-thinning medicines); prescription antacids or anti-acid medicines; stopped heart medicines; or stopped proton pump inhibitors. Do not use if you are taking: warfarin, clopidogrel or clostracil (blood-thinning medicines); prescription antacids or anti-acid medicines; stopped heart medicines; or stopped proton pump inhibitors. 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)</p> |
|---|---|--|--|

Bottom Ply

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. **Repeat 14-Day Course (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 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 disintegration test 2. **Inactive ingredients** include silicon dioxide, FD&C blue no. 1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid copolymer dispersion, iron oxide (black), polyethylene glycol, croscellose, indium tinsulfide, strong ammonia solution, sugar spheres (which contain liquid glucose, starch (maize) and sucrose), wax, titanium dioxide, triethyl citrate and yellow iron oxide. **Questions or comments?** call 1-866-274-4121 (Monday - Friday 8:30 AM to 5:00 PM EST)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Carton)

CAREone®
NDC 60000-109-05
#Compare to the active ingredient
in Nexium® 24 HR
See new warning
ESOMEPRAZOLE MAGNESIUM
Delayed-Release Capsules USP 20 mg*
Acid Reducer
Treats Frequent Heartburn
May take 1 to 4 days for full effect
Capsules
24hr
14 Capsules
One 14-day Course of treatment

The image displays a 3D perspective of the CAREone ESOMEPRAZOLE MAGNESIUM 20 mg capsule container carton. The top panel is blue and white, featuring the CAREone logo and product name. The bottom panel is white with blue and red text, containing detailed drug facts, directions, and warnings. The carton is shown in an open, flat layout, revealing its internal structure and the placement of the capsules. The top panel includes the following text:

- CAREone®**
- ESOMEPRAZOLE MAGNESIUM**
- Delayed-Release Capsules USP 20 mg***
- Acid Reducer**
- Compare to the active ingredient in Nexium® 24 HR**
- See new warning**
- ESOMEPRAZOLE MAGNESIUM**
- Delayed-Release Capsules USP 20 mg***
- Acid Reducer**
- Treats Frequent Heartburn**
- May take 1 to 4 days for full effect**
- 24hr**
- 14 CAPSULES**
- One 14-day course of treatment**

The bottom panel contains detailed drug facts, directions, and warnings. The drug facts section includes information on what to do if you miss a dose, what to do if you are allergic to esomeprazole, and what to do if you are pregnant or breast-feeding. The directions section includes information on how to take the capsules and how long to take them for. The warnings section includes information on what to do if you experience symptoms of a serious condition.

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60000-109 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ESOMEPRAZOLE MAGNESIUM DIHYDRATE (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT) | ESOMEPRAZOLE | 20 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM CARBONATE (UNII: 0E53J927NA) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SHELLAC (UNII: 46N107B71O) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| AMMONIA (UNII: 5138Q19F1X) | |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SUCROSE (UNII: C151H8M554) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|--------------|---------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | CAPSULE | Size | 14mm |

| Flavor | | Imprint Code | 181 | |
|------------------------------|--|---|----------------------|--------------------|
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:60000-109-05 | 1 in 1 CARTON | 10/16/2017 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:60000-109-03 | 3 in 1 CARTON | 10/16/2017 | |
| 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 | ANDA209339 | 10/16/2017 | | |

Labeler - Ahold U.S.A., Inc, (188910863)

Registrant - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(60000-109) , MANUFACTURE(60000-109) |

Revised: 4/2024

Ahold U.S.A., Inc,