

TOPCARE ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

Topco Associates LLC

Topco Associates LLC. Esomeprazole Magnesium Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22 mg esomeprazole magnesium dihydrate)

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 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
- 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)

Inactive ingredients

FD&C blue no. 1, FD&C blue no. 1 aluminum lake, FD&C red no. 3, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid and ethyl acrylate copolymer dispersion, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO NEXIUM[®] 24 HR

CLEAR MINIS[™]

ACTIVE INGREDIENT

SEE NEW WARNING INFORMATION

OUR PHARMACISTS RECOMMEND

Esomeprazole Magnesium

DELAYED RELEASE CAPSULES, 20 mg ACID REDUCER

MINI CAPSULES

24 HOUR

Treats Frequent Heartburn

May Take 1 to 4 Days for Full Effect

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT

actual size



TOPCARE ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-627 |
| 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 |
|------------------------------------|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

| | |
|---|--|
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MEGLUMINE (UNII: 6HG8UB2MUY) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SHELLAC (UNII: 46N107B71O) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | BLUE | Score | no score |
| Shape | CAPSULE | Size | 11mm |
| Flavor | | Imprint Code | 7U4 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:36800-627-01 | 1 in 1 CARTON | 03/12/2020 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:36800-627-03 | 3 in 1 CARTON | 03/12/2020 | |
| 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 | ANDA207193 | 03/12/2020 | |

Labeler - Topco Associates LLC (006935977)