DG HEALTH ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release

Dolgencorp Inc

Dolgencorp, 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.
- 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
- 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

acacia, D&C yellow #10, FD&C blue #1, FD&C red #3, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, menthol, methacrylic acid and ethyl acrylate copolymer dispersion, natural and artificial cool mint flavor, peppermint oil, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, spearmint oil, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-888-309-9030

Package/Label Principal Display Panel

DG® health

Compare to the active ingredient of Nexium® 24 HR

Esomeprazole Magnesium Delayed-Release Capsules, 20 mg

Acid Reducer

Treats Frequent Heartburn

24 HOUR

Releases a cooling sensation in mouth and throat

Cool Mint Flavor

Flavored Capsules

14 Capsules

One 14-Day Course of Treatment

Actual Capsule Size

May take 1 to 4 days for full effect



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
- If you are overweight, lose weight.
- If you smoke, quit smoking

Clinically Proven to Treat Frequent Heartburn

Drug Facts (continued)

- 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.

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Questions or comments? 1-888-309-9030

*This product is not manufactured or distributed Nexium® 24HR.

1 Bottle inside

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed! (888) 309-9030

Do Not Use if printed foil seal under cap or band around the center of each capsule is broken or missing.

DG[®] health

Compare to the active ingredient of Nexium® 24HR

Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg

Acid Reducer

Treats Frequent Heartburn



Releases a cooling sensation in mouth and throat

Cool Mint Flavor Flavored Capsules

14 Capsules

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DG HEALTH ESOMEPRAZOLE MAGNESIUM

ORAL

esomeprazole capsule, delayed release

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-640

Active Ingredient/Active Moiety

Basis of Strength Strength **Ingredient Name ESOMEPRAZOLE** (UNII: N3PA6559FT) (ESOMEPRAZOLE - UNII:N3PA6559FT) **ESOMEPRAZOLE** 20 mg

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ACACIA (UNII: 5C5403N26O) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MEGLUMINE (UNII: 6HG8UB2MUY) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SPEARMINT OIL (UNII: C3M81465G5) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

| Product Characteristics | | | |
|-------------------------|-------------------------------|--------------|----------|
| Color | BLUE (sealed with green band) | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | MINT | Imprint Code | L898 |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:55910-640- 01 | 1 in 1 CARTON | 05/03/2024 | |
| 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 | ANDA207193 | 05/03/2024 | |
| | | | |

Labeler - Dolgencorp Inc (068331990)

Revised: 5/2024 Dolgencorp Inc