# DG HEALTH ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release

Dolgencorp, LLC

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## **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

## 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

### 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?

1-888-309-9030

## Package/Label Principal Display Panel

SEE NEW WARNING INFORMATION

Compare to the active ingredient of Nexium<sup>®</sup> 24 HR Clear Minis ™

Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg

24 HOUR

Acid Reducer

Treats Frequent Heartburn

Mini Capsules

42 Mini Capsules

Three14-Day Courses of Treatment

20 mg

May take 1 to 4 days for full effect

Actual Capsule Size

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

Clinically Proven to Treat Frequent Heartburn

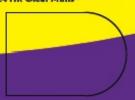
### Tips for Managing Heartburn

- 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 heard of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

## **DG**™ health

### SEE NEW WARNING INFORMATION

Compare to the active ingredient of Nexium® 24 HR Clear Minis™



3 Bottles inside

DG health

Esomeprazole Magnesium

14 M ini Capsules One 14-Day Coons of Treats

Delayed-Release Capsules, 20 mg Acid Reducer Treats Frequent Heartburn Capsul

# Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg

Acid Reducer

Treats Frequent Heartburn

Mini Capsules



May take 1 to 4 days for full effect

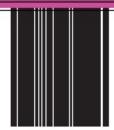






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### KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

#### Drug Facts

#### Active ingredient (in each capsule) Purpose

22 mg esomeprazole magnesium dihydrate)

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:

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- breathum with lightheadedness, sweating or dizziness

  chest pain or shoulder pain with shortness of breath; s weating; pain
  spreading to arms, neck or shoulders; or lightheadedness

#### 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 diamh ea you develop a: rash or joint pain

if pregnant or breast-feeding, ask a health profes sional 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 If the product is to the account of the account of

### Drug Facts (continued)

### Other information

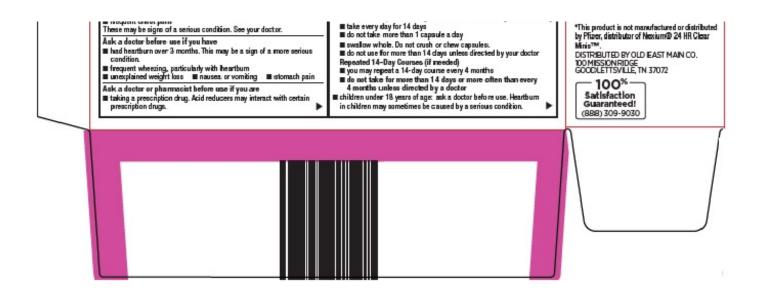
- before use

  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, femic oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid and ethyl acrylate copolymer dispersion, polyethylen glycol, polysorbate 90, shellar, sodium launyl sulfate, sugar spheres, talc, titanium dixxide, triethyl citrate

Questions or comments? 1-888-309-9030



## **DG HEALTH ESOMEPRAZOLE MAGNESIUM**

esomeprazole capsule, delayed release

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-250

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

ESOMEPRAZOLE (UNII: N3PA6559FT) (ESOMEPRAZOLE - UNII:N3PA6559FT)

ESOMEPRAZOLE (UNII: N3PA6559FT) (ESOMEPRAZOLE - UNII:N3PA6559FT)

| Ingredient Name  Strength  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  FERROSOFERRIC OXIDE (UNII: XM0M87F357)  GELATIN, UNSPECIFIED (UNII: 2G86QN327L)  GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)  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: 3WQ0SDW1A)  POLYSORBATE 80 (UNII: 6OZP39ZG8H)  SHELLAC (UNII: 46N107B71O)  SODIUM LAURYL SULFATE (UNII: 368GB5141J)  TALC (UNII: 7SEV7J4R1U)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  TRIETHYL CITRATE (UNII: 8Z96QXD6UM) |   |          |
|---|---|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  FERROSOFERRIC OXIDE (UNII: XM0M87F357)  GELATIN, UNSPECIFIED (UNII: 2G86QN327L)  GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)  HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)  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: 46N107B710)  SODIUM LAURYL SULFATE (UNII: 368GB5141J)  TALC (UNII: 7SEV7J4R1U)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  | Inactive Ingredients  |          |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  FERROSOFERRIC OXIDE (UNII: XM0M87F357)  GELATIN, UNSPECIFIED (UNII: 2G86QN327L)  GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)  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: 46N107B710)  SODIUM LAURYL SULFATE (UNII: 368GB5141J)  TALC (UNII: 7SEV7J4R1U)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  | Ingredient Name   | Strength |
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| TALC (UNII: 7SEV7J4R1U)  TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  | SHELLAC (UNII: 46N107B710)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   | SODIUM LAURYL SULFATE (UNII: 368GB5141J)                                    |          |
|   | TALC (UNII: 7SEV7J4R1U)   |          |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM)   | TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |          |
|   | TRIETHYL CITRATE (UNII: 8Z96QXD6UM)   |          |

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

| P | Packaging            |   |                         |                       |  |  |  |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|
| # | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |  |  |
| 1 | NDC:55910-250-<br>01 | 1 in 1 CARTON                                     | 07/14/2020              |                       |  |  |  |
| 1 |                      | 14 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |  |  |
| 2 | NDC:55910-250-<br>02 | 2 in 1 CARTON                                     | 07/14/2020              |                       |  |  |  |
| 2 |                      | 14 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |  |  |
| 3 | NDC:55910-250-<br>03 | 3 in 1 CARTON                                     | 03/18/2021              |                       |  |  |  |
| 3 |                      | 14 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |  |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| ANDA                  | ANDA207193                                  | 07/14/2020              |                       |  |  |
|                       |   |                         |                       |  |  |

## Labeler - Dolgencorp, LLC (068331990)

Revised: 3/2021 Dolgencorp, LLC