

# **GOOD SENSE ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release**

**L. Perrigo Company**

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## **Perrigo 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?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

GOODSENSE®

Flavored Capsules

24HR

Esomeprazole Magnesium

Actual Size

Delayed-Release Capsules 20 mg

Acid Reducer

Cool Mint Flavor

Treats Frequent Heartburn

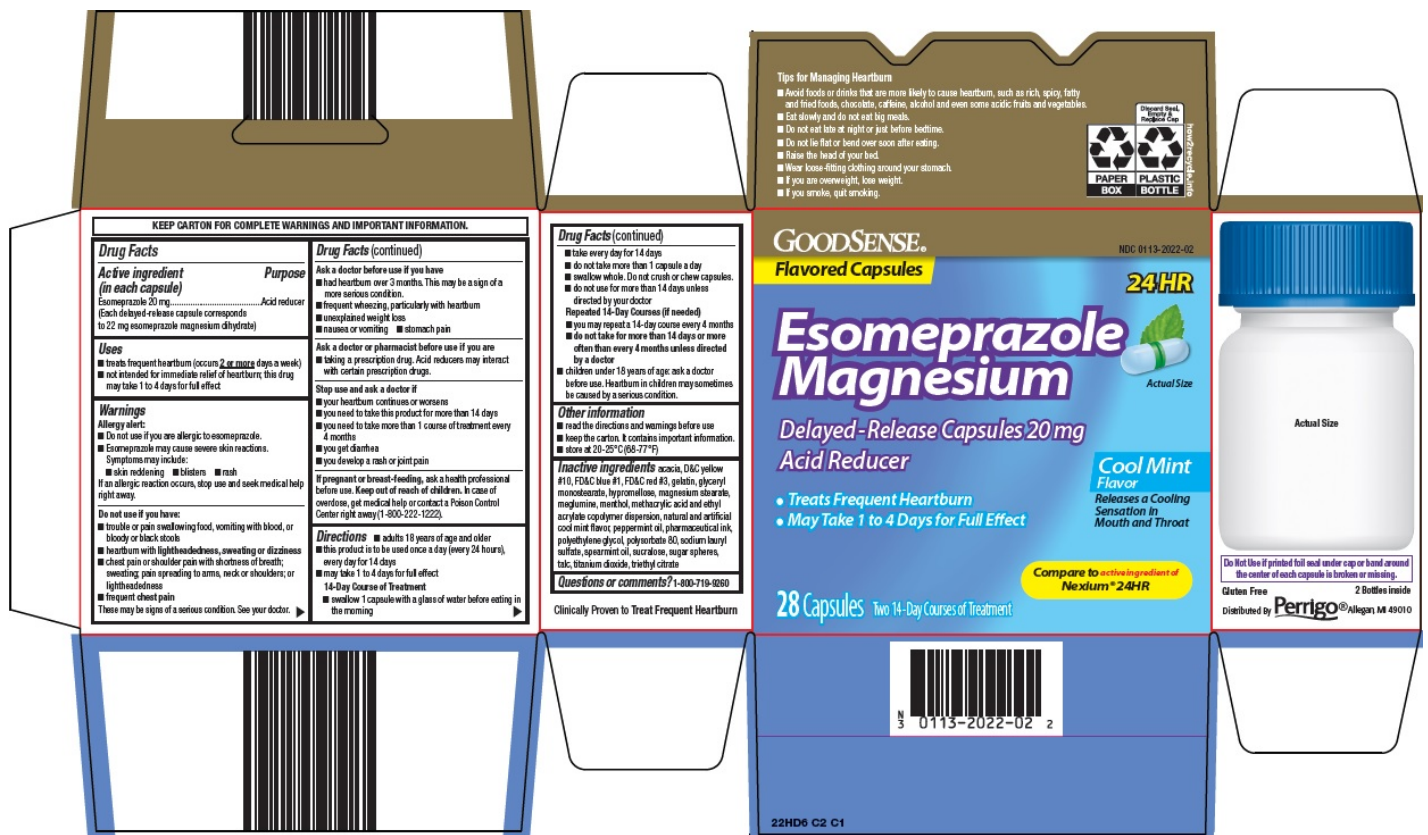
May Take 1 to 4 Days for Full Effect

Releases a Cooling Sensation in Mouth and Throat

Compare to active ingredient of Nexium® 24HR

28 Capsules

Two 14-Day Courses of Treatment



## GOOD SENSE ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-2022
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	BLUE (sealed with green band)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	L898
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-2022-02	2 in 1 CARTON	04/24/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0113-2022-01	14 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207193	04/24/2024	

**Labeler** - L. Perrigo Company (006013346)

Revised: 5/2024

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