

SOUND BODY ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release

Big Lots Stores, Inc.

Big Lots, Inc 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 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?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the Active Ingredient in Nexium® 24 HR

Treats Frequent Heartburn

CAPSULES

Esomeprazole Magnesium

See New Warning Information

Delayed-Release Capsules, 20 mg

Acid Reducer

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

24 HOUR

3 BOTTLES -14 CAPSULES EACH

42 TOTAL CAPSULES

Three 14-day courses of treatment

Actual Size



Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg
Acid Reducer



Compare to the Active
Ingredient in Nexium® 24 HR*

Treats Frequent Heartburn

Esomeprazole Magnesium

Delayed-Release Capsules, 20 mg
Acid Reducer

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

3 BOTTLES - 14 CAPSULES EACH
42 TOTAL CAPSULES

Three 14-day courses of treatment

CAPSULES

See New
Warning
Information



3 BOTTLES INSIDE



ACTUAL SIZE

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

*This product is not manufactured or distributed by
Pfizer, distributor of Nexium® 24 HR.

GLUTEN FREE



3 70030 26609 8

Packaged by
Perrigo Company Inc.
Big Lots Stores, Inc.
P.O. Box 28523
Columbus, OH
43228-0523
W95003185 ITEM#89807

898D7 TM C1

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

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Drug Facts (continued)

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- you need to take more than 1 course of treatment every 4 months
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Drug Facts (continued)

Inactive ingredients

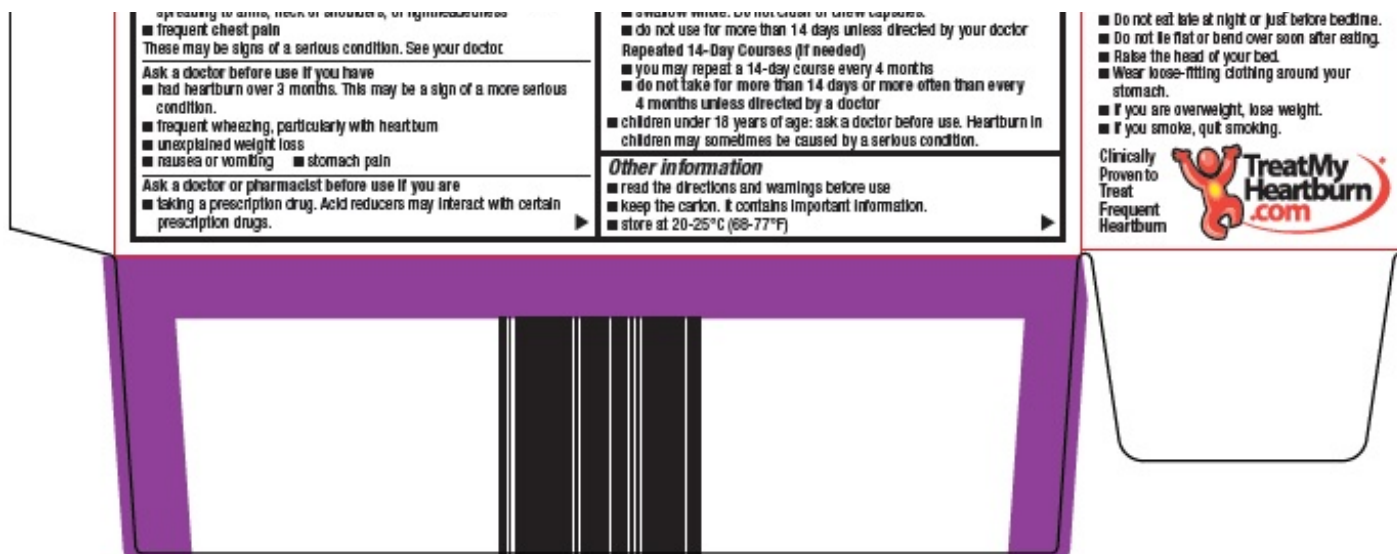
FD&C blue no. 1, FD&C red no. 3, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid and ethyl acrylate copolymer dispersion, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9280

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.



SOUND BODY ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50594-029 |
| 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 |
|--|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6130) | |
| MEGLUMINE (UNII: 6HG8UB2MUY) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SHELLAC (UNII: 46N107B710) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|-----------------|------------------|---------------------|----------|
| Color | BLUE (opaque) | Score | no score |
| Shape | CAPSULE (oblong) | Size | 14mm |
| Flavor | | Imprint Code | L898 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50594-029-01 | 1 in 1 CARTON | 03/26/2018 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:50594-029-03 | 3 in 1 CARTON | 04/12/2021 | |
| 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 | 03/26/2018 | |

Labeler - Big Lots Stores, Inc. (017885351)

Revised: 4/2021

Big Lots Stores, Inc.