

ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release
Publix Super Markets Inc

Publix Super Markets, 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.
- 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 68-77°F (20-25°C)

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

Package/Label Principal Display Panel

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SEE NEW WARNING INFORMATION

24 HR

esomeprazole magnesium

DELAYED-RELEASE CAPSULES 20 mg

ACID REDUCER

CAPSULES

- Treats frequent heartburn
- May take 1 to 4 days for full effect
- Three 14-day courses of treatment

ACTUAL SIZE

42 CAPSULES

Compare to Nexium® 24HR active ingredient.

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts
Active Ingredient (in each capsule) Esomeprazole 20 mg
Purpose Acid reducer
 (Each delayed-release capsule corresponds to 20 mg esomeprazole magnesium (hydrate))

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
Warning alert:
 ■ Esomeprazole may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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

Drug Facts (continued)
 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

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 68°-77°F (20°-25°C)

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, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Tips for Managing Heartburn
 ■ Avoid foods or drinks that are more likely to cause heartburn, such as rich, greasy, fatty and fried foods, chocolate, coffee, 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.
 ■ Wear loose-fitting clothing around your stomach.
 ■ If you are overweight, lose weight.
 ■ If you smoke, quit smoking.

24 HR
esomeprazole magnesium
 DELAYED-RELEASE CAPSULES 20 mg
 ACID REDUCER

42 CAPSULES

3 Bottles Inside

esomeprazole magnesium
 24 HR
 DELAYED-RELEASE CAPSULES 20 mg
 ACID REDUCER
 14 CAPSULES

Compare to Nexium® 24HR active ingredient.*

Publix

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398D7 63 C4

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

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PUBLIC GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56062-898 |
| 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: 70097M6I30) | |
| MEGLUMINE (UNII: 6HG8UB2MUJ) | |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (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 (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:56062-898-01 | 1 in 1 CARTON | 09/29/2017 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|---|------------|--|
| 2 | NDC:56062-898-02 | 2 in 1 CARTON | 09/29/2017 | |
| 2 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:56062-898-03 | 3 in 1 CARTON | 09/29/2017 | |
| 3 | | 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 | 09/29/2017 | |

Labeler - Publix Super Markets Inc (006922009)

Revised: 9/2025

Publix Super Markets Inc