

ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release
Walgreen Company

Walgreen Co. Esomeprazole Magnesium Delayed Release Capsules, 20 mg
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 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?

1-800-719-9260

Package/Label Principal Display Panel

Treats frequent heartburn

Walgreens

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

WALGREENS PHARMACIST RECOMMENDED

Esomeprazole Magnesium

DELAYED RELEASE CAPSULES 20 mg / ACID REDUCER

24 HOUR Mini Capsules

42 MINI CAPSULES

THREE 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

ACTUAL SIZE

SEE NEW WARNING INFORMATION

Walgreens



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

Esomeprazole Magnesium

DELAYED RELEASE CAPSULES 20 mg / ACID REDUCER

Treats frequent heartburn

NDC 0363-1699-03



Walgreens



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Esomeprazole Magnesium

DELAYED RELEASE CAPSULES 20 mg / ACID REDUCER

24 HOUR

Mini Capsules



ACTUAL SIZE

42

MINI CAPSULES

THREE 14-DAY COURSES OF TREATMENT
MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

SEE NEW WARNING INFORMATION

3 BOTTLES INSIDE

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

Clinically Proven to
Treat Frequent Heartburn



how2recycle.com

DO NOT USE IF PRINTED FOIL SEAL UNDER
CAP OR BAND AROUND THE CENTER OF
EACH CAPSULE IS BROKEN OR MISSING.

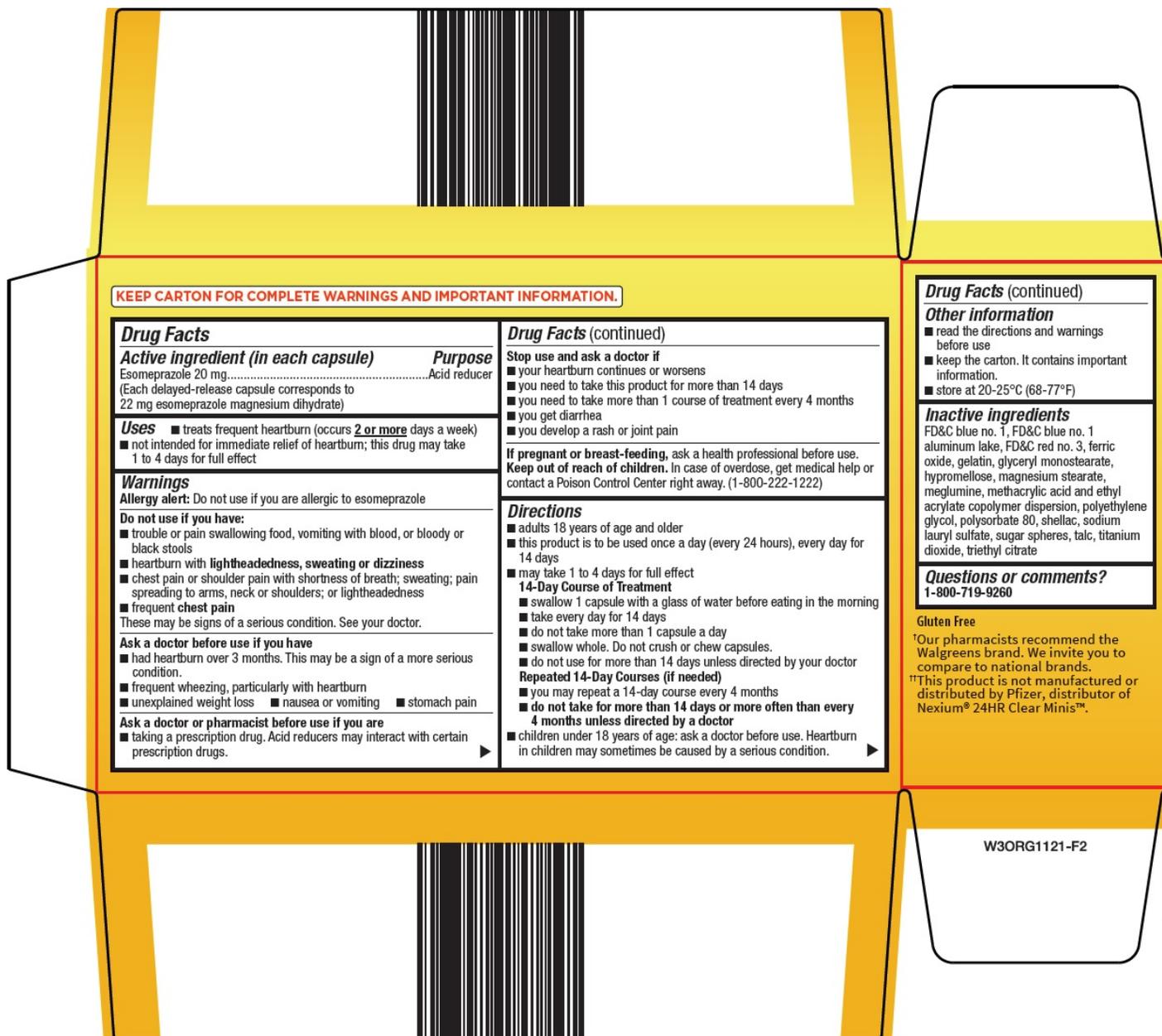
DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com
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ITEM 631703 W10106-0622-L



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KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

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 - frequent chest pain
- These may be signs of a serious condition. See your doctor.

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- frequent wheezing, particularly with heartburn
- unexplained weight loss ■ nausea or vomiting ■ stomach pain

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Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

Gluten Free

[†]Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

^{††}This product is not manufactured or distributed by Pfizer, distributor of Nexium® 24HR Clear Minis™.

W3ORG1121-F2

ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-1699 |
| 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) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MEGLUMINE (UNII: 6HG8UB2MUJ) | |
| 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) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-1699-01 | 1 in 1 CARTON | 03/22/2020 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:0363-1699-03 | 3 in 1 CARTON | 03/26/2020 | |
| 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 | 03/22/2020 | |

Labeler - Walgreen Company (008965063)