

ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release

Walgreen Company

Walgreen Co. 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

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

Walgreens

•WALGREENS• PHARMACIST RECOMMENDED

Compare to the active ingredient in Nexium® 24HR

Cool Mint Flavored Capsules

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour

•Treats frequent heartburn

•Releases a cooling sensation in mouth & throat

42 CAPSULES

THREE 14-DAY COURSES OF TREATMENT

ACTUAL SIZE

Cool Mint flavor

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

Walgreens



Compare to the active ingredient in Nexium® 24HR[†]

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

NDC 0363-7223-03

Cool Mint Flavored Capsules

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour

- Treats frequent heartburn
- Releases a cooling sensation in mouth & throat

42

CAPSULES

THREE 14-DAY COURSES OF TREATMENT



ACTUAL SIZE



Cool Mint flavor



Walgreens

NDC 0363-7223-01

Cool Mint Flavored Capsules

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES 20 mg / ACID REDUCER

24 Hour

- Treats frequent heartburn
- Releases a cooling sensation in mouth and throat

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



Cool Mint flavor

ACTUAL SIZE
3 BOTTLES INSIDE

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

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

^{††}This product is not manufactured or distributed by AstraZeneca AB Corporation, owner of the registered trademark Nexium®.

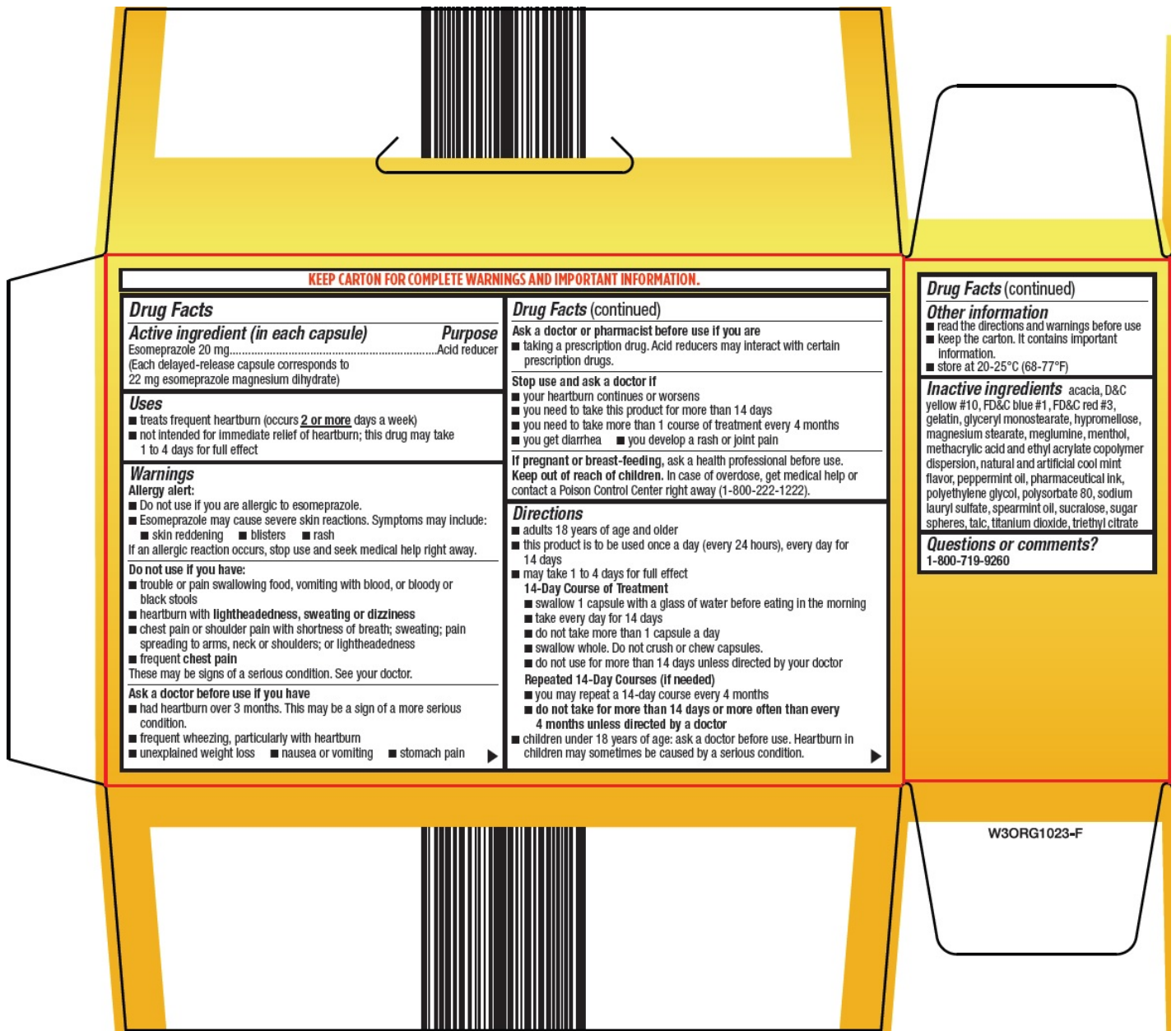


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ITEM 618611 W10106-0224-L



22HD7 94 C-1



KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts

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- If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have:

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 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent chest pain
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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

W3ORG1023-F

ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-7223
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: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SPEARMINT OIL (UNII: C3M81465G5)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7223-03	3 in 1 CARTON	03/14/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-7223-01	14 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207193	03/14/2024	

Labeler - Walgreen Company (008965063)

