

# **ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release**

**Walgreens Company**

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## **Drug Facts**

### **Active ingredient(s) in each capsule**

\*Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, USP)

### **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 lightheadness
- 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**

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

**Stop use and ask 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**

- each capsule contains: magnesium, 15 mg
- read directions and warnings before use
- keep the carton. It contains important information
- store at 20 to 25°C (68 to 77°F)

**Inactive ingredients**

acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, poloxamer, polysorbate 80, povidone, potassium hydroxide, propylene glycol, shellac, sugar, talc, titanium dioxide

## **Questions or comments**

call toll-free weekdays 9 AM to 7 PM EST at 1-888-375-3784

## **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.

## **Container Label**

Container Label:

Walgreens

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

# Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg\* ACID REDUCER

24 Hour Capsules

• Treats Frequent Heartburn

**14** CAPSULES

ONE 14-DAY COURSE OF TREATMENT

NDC 0383-3298-14

**TAMPER-EVIDENT FEATURES: Do not use if foil seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or black band around the center of each capsule is broken or missing.**

**KEEP CAPSULES COMPLETELY DRY AND AWAY FROM MOISTURE.**

## Active ingredient (in each capsule)

Esomeprazole 20 mg, ..... Acid reducer (Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, USP)

**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

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LOT/EXP 150090769

PEEL HERE

## Reseal Area

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

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## 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

■ each capsule contains: magnesium, 15 mg ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20°C to 25°C (68°F to 77°F)

## Inactive ingredients

acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, poloxamer, polyorbate 80, povidone, potassium hydroxide, propylene glycol, shellac, sugar, talc, titanium dioxide

## Questions or comments? call

toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784 W3ORG0922-F REV-0922

ITEM 978546 W00000-0000-0

Carton label



**Drug Facts**  
**Active ingredient (for each capsule)** Esomeprazole 20 mg  
**Purpose** Acid reducer  
**Uses** Treats frequent heartburn (occurs 2 or more days a week)  
**Warnings** Allergy alert: Do not use if you are allergic to esomeprazole  
**Other information** Each capsule contains magnesium, 15 mg

**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.

**Keep Carton for Complete Warnings and Important Information.**

**WALGREENS**

**Esomeprazole Magnesium**  
DELAYED-RELEASE CAPSULES USP, 20 mg\* / ACID REDUCER

**3 BOTTLES INSIDE**  
42 CAPSULES TOTAL





LOT  
EXP

WJ0RG922-F  
REV-0922

**42 CAPSULES**  
THREE 14-DAY COURSES OF TREATMENT

**24 Hour Capsules**  
Treats Frequent Heartburn

**WALGREENS**

**Esomeprazole Magnesium**  
DELAYED-RELEASE CAPSULES USP, 20 mg\* / ACID REDUCER

**42 CAPSULES**  
THREE 14-DAY COURSES OF TREATMENT

ITEM 978548 W00000-0000-0  
100% SATISFACTION GUARANTEED  
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MADE IN INDIA



# ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-3298(NDC:43598-407)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Esomeprazole Magnesium</b> (UNII: R6DXU4WAY9) (Esomeprazole - UNII:N3PA6559FT)	Esomeprazole	20 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>acetyltributyl citrate</b> (UNII: 0ZBX0N59RZ)	
<b>Dibutyl Sebacate</b> (UNII: 4W5IH7FLNY)	
<b>Ferrosoferric Oxide</b> (UNII: XM0M87F357)	
<b>Gelatin</b> (UNII: 2G86QN327L)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>Magnesium Oxide</b> (UNII: 3A3U0GI71G)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A</b> (UNII: NX76LV5T8J)	
<b>Poloxamer 188</b> (UNII: LQA7B6G8JG)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Povidone K30</b> (UNII: U725QWY32X)	

<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>Potassium Hydroxide</b> (UNII: WZH3C48M4T)	
<b>Shellac</b> (UNII: 46N107B71O)	
<b>Sucrose</b> (UNII: C151H8M554)	
<b>Fd&amp;C Blue No. 1</b> (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	BLUE (light blue cap) , BLUE (dark blue body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	RDY;327
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-3298-14	1 in 1 CARTON	12/31/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-3298-28	2 in 1 CARTON	12/31/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-3298-42	3 in 1 CARTON	12/31/2018	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0363-3298-01	3 in 1 CARTON	12/01/2019	
4		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	ANDA207673	12/31/2018	

**Labeler** - Walgreens Company (008965063)