

**ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release**  
**CHAIN DRUG MARKETING ASSOCIATION INC**

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**Drug Facts**

**Active ingredient (in each capsule)**

\*Esomeprazole 20 mg

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

**Purpose**

Acid reducer

**Use(s)**

- 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 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**

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- diazepam (anxiety medicine)
- tacrolimus or mycophenolate mofetil (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

**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.

### **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.

**Bottle Label**

NDC 63868-425-14

QC QUALITY CHOICE

Treats **Frequent** Heartburn

May take **1 to 4 days**

**for full effect**

**Esomeprazole**

**Magnesium**

**Delayed-Release**

**Capsules USP, 20 mg\***

**Acid Reducer 24 HOUR**

**14 Capsules**

One 14-Day Course of Treatment



NDC 63868-425-14

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Capsules USP, 20 mg\***Acid Reducer 24 HOUR****14 Capsules**

One 14-Day Course of Treatment

Do not use if seal under bottle cap imprinted  
with "SEALED for YOUR PROTECTION"  
or black band around the center of  
each capsule is broken or missing**IMPORTANT: KEEP CARTON FOR COMPLETE  
WARNINGS AND IMPORTANT INFORMATION.****Drug Facts****Active ingredient Purpose  
(in each capsule)**Esomeprazole 20 mg.....Acid reducer  
(Each delayed-release capsule  
corresponds to 20.7 mg  
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- trouble or pain swallowing food,
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black stools
- heartburn with  
lightheadedness, sweating or  
dizziness

Distributed by C.D.M.A., Inc.®  
43157 W 9 Mile Rd Novi, MI 48375  
www.qualitychoice.com  
Questions: 800-935-2362

Made in India

LOT/EXP

150076708

PEEL  
HERE**Drug Facts (continued)**

- 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).**Drug Facts (continued)****Directions**

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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 8 AM to 10 PM EST at  
1-888-375-3784**Carton Label**

NDC 63868-425-14

QC QUALITY CHOICE

\*\*Compare to the  
Active Ingredient in  
Nexium® 24HRTreats **Frequent** Heartburn  
May take 1 to 4 days  
for full effect**Esomeprazole  
Magnesium****Delayed-Release  
Capsules USP, 20 mg\*****Acid Reducer****24 HOUR**

14 Capsules  
One 14-Day Course of Treatment



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- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

**TAMPER EVIDENT:** 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.

**Clinically Proven to Treat Frequent Heartburn**

**Drug Facts (continued)**

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**Questions or comments?**

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**\*\*This product is not manufactured or distributed by Pfizer Inc., distributor of Nexium® 24HR. Nexium® is a registered trademark of AstraZeneca AB.**

**IMPORTANT: Keep carton for complete warnings and important information.**

**Made in India**

NDC 63868-425-14

**QC QUALITY CHOICE**

**\*\*Compare to the Active Ingredient in Nexium® 24HR**

**Treats Frequent Heartburn**  
May take **1 to 4 days** for full effect

**Esomeprazole Magnesium**

**Delayed-Release Capsules USP, 20 mg\***

**Acid Reducer**

**24 HOUR**

actual size 

**14 Capsules**  
One 14-Day Course of Treatment

**1 BOTTLE INSIDE**

**Drug Facts**

Active ingredient (in each capsule)	Purpose
Esomeprazole 20 mg	Acid reducer

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- frequent chest pain

These may be signs of a serious condition. See your doctor.



**LOT**

**EXP**

**6 35515 99635 9**

**100% SATISFACTION GUARANTEED**

Distributed by C.D.M.A., Inc.  
4357 W 9 Mile Rd  
Nexi, MI 48575  
www.qualitychoice.com  
Questions: 800-935-2362

## ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-425(NDC:43598-407)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name			Strength	
acetyltributyl citrate (UNII: 0ZBX0N59RZ)				
Dibutyl Sebacate (UNII: 4W5IH7FLNY)				
Ferrosoferric Oxide (UNII: XM0M87F357)				
Gelatin (UNII: 2G86QN327L)				
Glyceryl Monostearate (UNII: 230OU9XXE4)				
Hypromelloses (UNII: 3NXW29V3WO)				
Magnesium Oxide (UNII: 3A3U0GI71G)				
Magnesium Stearate (UNII: 70097M6I30)				
Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A (UNII: NX76LV5T8J)				
Poloxamer 188 (UNII: LQA7B6G8JG)				
Polysorbate 80 (UNII: 6OZP39ZG8H)				
Povidone K30 (UNII: U725QWY32X)				
Talc (UNII: 7SEV7J4R1U)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Potassium Hydroxide (UNII: WZH3C48M4T)				
Shellac (UNII: 46N107B71O)				
Sucrose (UNII: C151H8M554)				
Fd&C Blue No. 1 (UNII: H3R47K3TBD)				
Product Characteristics				
Color	BLUE (light blue cap) , BLUE (dark blue body)	Score	no score	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code	RDY;327	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-425-14	1 in 1 CARTON	07/06/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-425-28	2 in 1 CARTON	03/15/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63868-425-42	3 in 1 CARTON	07/06/2018	
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	ANDA207673	07/06/2018		

**Labeler** - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)