

# **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

- 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 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 8 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

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

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

**IMPORTANT: KEEP CARTON FOR COMPLETE  
WARNINGS AND IMPORTANT INFORMATION.**

### Active ingredient Purpose (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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Novi, MI 48375  
www.qualitychoice.com  
Questions: 800-935-2362  
REV 11/2022  
Made in India

LOT/EXP 150091516

PEEL  
HERE

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** ■ 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

## Carton Label

NDC 63868-425-42

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

42 Capsules

Three 14-Day Courses of Treatment

**Clinically Proven to Treat Frequent Heartburn**

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

**25616001**

**Drug Facts**  
**Active ingredient (in each capsule)** Acid reducer (Each delayed-release capsule corresponds to 20 mg esomeprazole magnesium USP)

**Warnings**  
Allergy alert: Do not use if you are allergic to esomeprazole  
Contraindications may cause severe side reactions. Symptoms may include: skin redness, hives, 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 light-headedness, dizziness or dizziness  
● chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders or light-headedness  
● 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.  
● 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

**Drug Facts (continued)**  
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  
● you 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 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**  
methyltriethylsiloxane, diethyl sebacate, FD&C Blue #1, ferrous feric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer type III, polyethylene glycol, polyethylene glycol, potassium hydroxide, polyethylene glycol, sugar, 10, titanium dioxide

**Questions or comments?**  
Call toll-free weekdays 9 AM to 6 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.

**KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION**  
● This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Nexium® 24HR. Nexium® is a registered trademark of AstraZeneca AB.

**QUALITY CHOICE**

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

**Acid Reducer**  
24 HOUR actual size

**42 Capsules**  
Three 14-Day Courses of Treatment

**3 BOTTLES INSIDE**

**LOT**  
**EXP**

**6 35515 99630 6**

## ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-425(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: OZ BX0N59RZ)	
<b>Dibutyl Sebacate</b> (UNII: 4W5IH7FLNY)	
<b>Ferrosoferric Oxide</b> (UNII: XMOM87F357)	
<b>Gelatin</b> (UNII: 2G86QN327L)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>Magnesium Oxide</b> (UNII: 3A3U0G171G)	
<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: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)