

**ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release**  
**Meijer Distribution Inc**

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**Meijer Distribution, Inc. 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

**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 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**

Compare to Nexium<sup>®</sup> 24 HR active ingredient

24 HOUR

esomeprazole magnesium

Delayed-Release Capsules, 20 mg | Acid Reducer

SEE NEW WARNING INFORMATION

Treats Frequent Heartburn

CAPSULES

28 Capsules

Two 14-day courses of treatment

May take 1 to 4 days for full effect

actual size

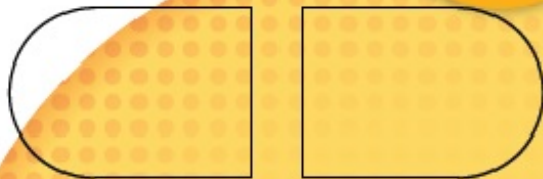
### Tips for Managing Heartburn

- 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

**meijer**

NDC 41250-000-02  
Compare to  
Nexium® 24 HR  
active ingredient\*



24 HOUR  
**esomeprazole  
magnesium**

Delayed-Release Capsules, 20 mg | Acid Reducer

SEE NEW WARNING  
INFORMATION  
CAPSULES

Treats Frequent Heartburn

**28 Capsules**

Two 14-day courses of treatment  
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actual size

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



actual size  
2 bottles inside

DIST. BY MEIJER  
DISTRIBUTION, INC.  
GRAND RAPIDS, MI  
49544  
www.meijer.com



PID 4039776



998D6 6E C5

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

#### Drug Facts

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- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating, or dizziness

#### Drug Facts (continued)

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

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- you need to take more than 1 course of treatment every 4 months
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#### Directions

#### Drug Facts (continued)

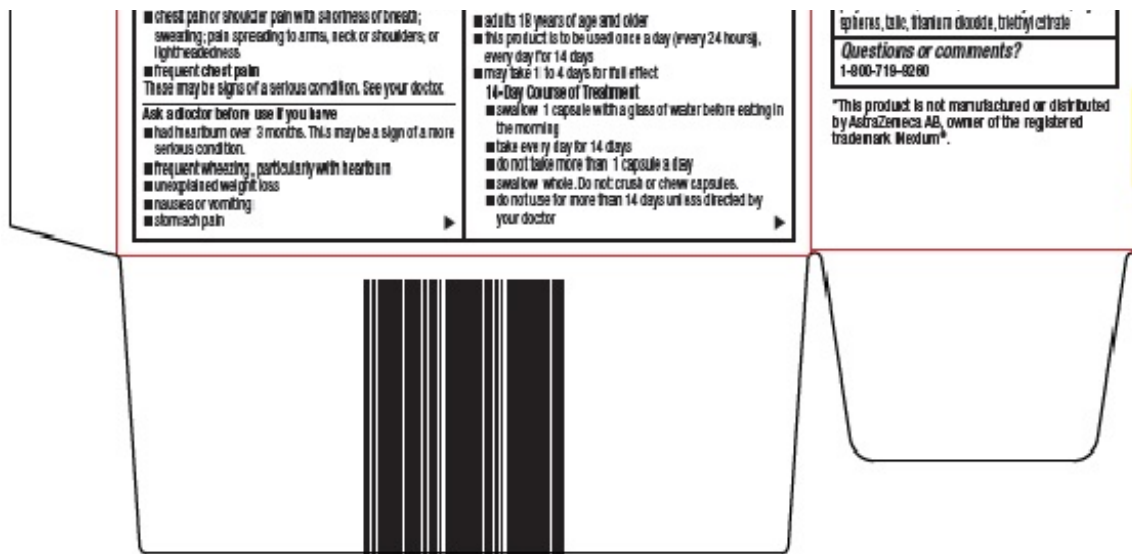
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often than every 4 months unless directed  
by a doctor

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**Inactive ingredients:** FD&C blue no. 1,  
FD&C red no. 3, ferric oxide, gelatin, glyceryl  
monostearate, hypromellose, magnesium stearate,  
magnesium, methacrylic acid and ethyl acrylate  
copolymer dispersion, polyethylene glycol,  
polyorbate 80, shellac, sodium lauryl sulfate, sugar



## ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-900
<b>Route of Administration</b>	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: HBR47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MU9)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B710)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

**Product Characteristics**

<b>Color</b>	BLUE (opaque)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	L898
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-900-01	1 in 1 CARTON	09/22/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41250-900-02	2 in 1 CARTON	09/22/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41250-900-03	3 in 1 CARTON	09/22/2017	
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	ANDA207193	09/22/2017	

**Labeler** - Meijer Distribution Inc (006959555)

Revised: 3/2020

Meijer Distribution Inc