

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

**Topco Associates LLC**

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## **Topco Associated LLC. 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?**

**1-888-423-0139**

**Package/Label Principal Display Panel**

TopCare® health

COMPARE TO NEXIUM® 24 HR ACTIVE INGREDIENT

Esomeprazole Magnesium

DELAYED RELEASE CAPSULES, 20 mg

ACID REDUCER CAPSULES

24 HOUR

- Treats Frequent Heartburn
- May Take 1 to 4 Days for Full Effect

14 CAPSULES

ONE-14 DAY COURSE OF TREATMENT

actual size



## TOPCARE ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-636
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>MEGLUMINE</b> (UNII: 6HG8UB2MUY)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>SHELLAC</b> (UNII: 46N107B71O)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIETHYL CITRATE</b> (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:36800-636-01	1 in 1 CARTON	09/22/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-636-02	2 in 1 CARTON	09/22/2017	08/31/2019
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:36800-636-03	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** - Topco Associates LLC (006935977)