

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

**Topco Associates LLC**

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**Topco Associates 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 blue no. 1 aluminum lake, 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 CLEAR MINIS™ ACTIVE INGREDIENT

Esomeprazole Magnesium

DELAYED RELEASE CAPSULES, 20 mg ACID REDUCER

24 HOUR

MINI CAPSULES

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

42 CAPSULES

THREE 14-DAY COURSES OF TREATMENT

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



NDC 36800-627-03

**TopCare**  
health

COMPARE TO NEXIUM® 24 HR CLEAR  
MINIS™ ACTIVE INGREDIENT\*



# Esomeprazole Magnesium

DELAYED RELEASE CAPSULES, 20 mg ACID REDUCER



## MINI CAPSULES

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

**42 CAPSULES**

THREE 14-DAY COURSES OF TREATMENT

actual  
size



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



\*This product is not manufactured or distributed by Pfizer, distributor of Nexium® 24 HR Clear Minis™.

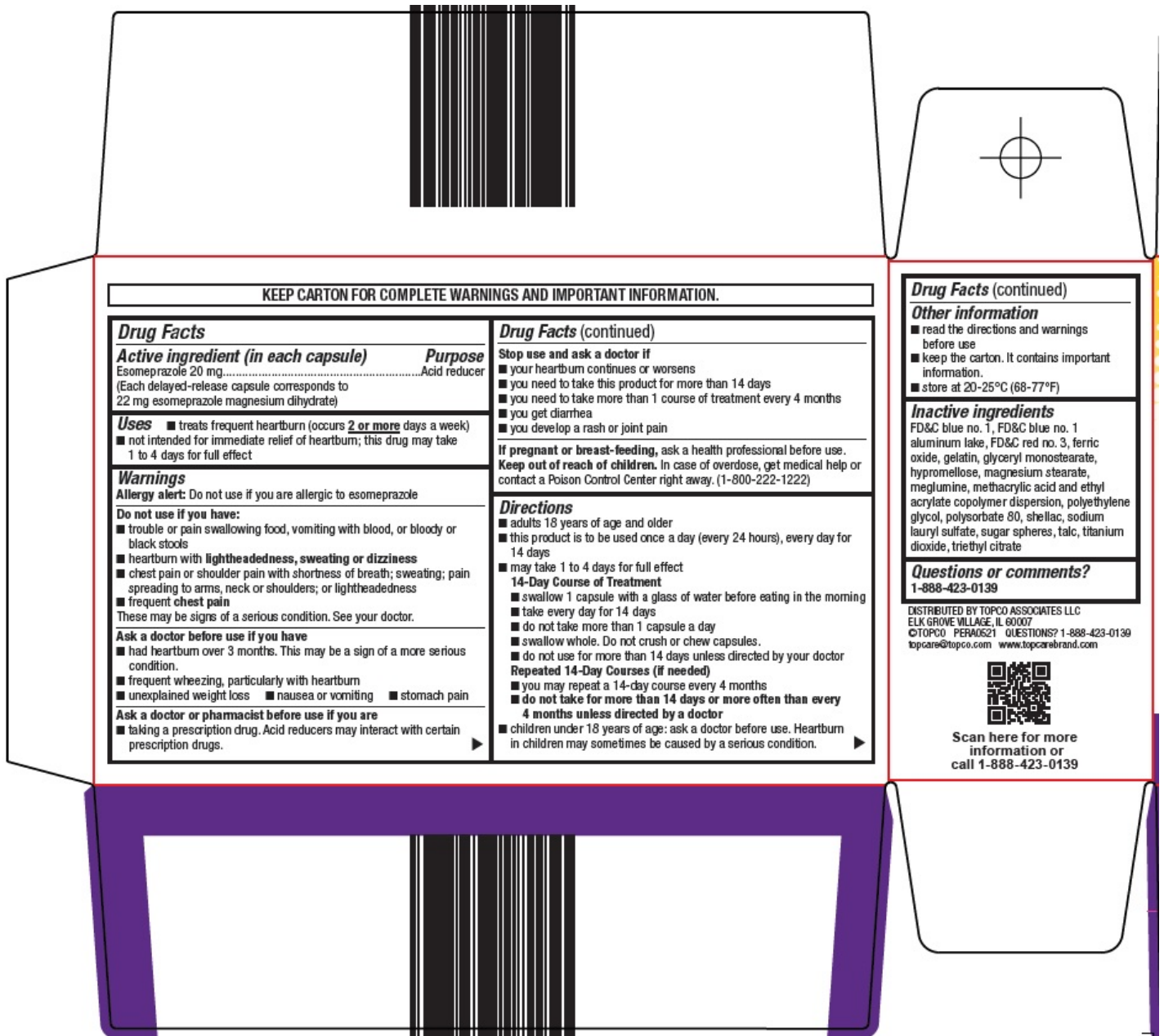
**CODE AREA**

7U4D7 88 C3



Do Not Use if printed foil seal under cap or band around the center of each capsule is broken or missing.





## TOPCARE ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-627
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ESOMEPRAZOLE MAGNESIUM DIHYDRATE</b> (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MUJ)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	7U4
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-627-01	1 in 1 CARTON	03/12/2020	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-627-03	3 in 1 CARTON	03/12/2020	
2		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	03/12/2020	

**Labeler** - Topco Associates LLC (006935977)