# SIGNATURE CARE ESOMEPRAZOLE MAGNESIUM- esomeprazole capsule, delayed release Safeway

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### **Better Living Brands 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 <u>2 or more</u> 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?

1-800-719-9260

## Package/Label Principal Display Panel

SEE NEW WARNING INFORMATION

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

**Quality Guaranteed** 

Mini Capsules

24 HOUR

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES, 20 mg

Acid Reducer

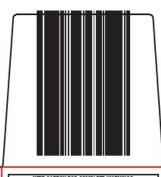
Treats frequent heartburn

Actual Size

May take 1 to 4 days for full effect

14 MINI CAPSULES

One 14-day course of treatment



#### Tips for Managing Heartburn

- Ilps for Managing Hearthurn

   Avoid foods or drinks that are more likely to cause hearthurn, such as rich, spicy fatty and fried foods, chocotate, caffeine, atochol and even some acidic fruits and vegetables.

   Eat slowly and do not eat big meels.

   Do not at late at right or just before bedrime.

   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, bes weight.

- If you are overweight, lose weight.

  If you smoke, quit smoking.
- Clinically Proven to Treat Frequent Heartburn



Scan here for more inform

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

### KEEP CARTON FOR COMPLETE WARNINGS and important information.

#### Drug Facts

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#### Drug Facts (continued)

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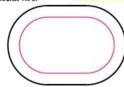
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Questions or comments? 1-900-719-9260

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











DELAYED-RELEASE CAPSULES, 20 mg Acid Reducer

Actual Size Treats frequent hearthurn May take 1 to 4 days for

14 MINI CAPSULES



PO. BOX 99, PLEASANTON, CA 94596-0009 1-888-723-3829 www.betterlivingbrandsLLC.co







7U4D5 LJ C1

### SIGNATURE CARE ESOMEPRAZOLE MAGNESIUM

esomeprazole capsule, delayed release

### **Product Information**

HUMAN OTC DRUG NDC:21130-714 Product Type Item Code (Source)

ORAL Route of Administration

#### **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: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6 HG8 UB2MUY)	
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 DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

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

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:21130-714-01	1 in 1 CARTON	07/02/2020		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:21130-714-03	3 in 1 CARTON	07/02/2020		
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	07/02/2020		

# **Labeler -** Safeway (009137209)

Revised: 7/2020 Safeway