

**HARRIS TEETER ACID REDUCER- esomeprazole capsule, delayed release**  
**Harris Teeter, LLC**

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**Harris Teeter, LLC Acid Reducer 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**

See New Warning Information

Esomeprazole Magnesium Delayed-Release Capsules, 20 mg

ACID REDUCER

Treats Frequent Heartburn

May take 1 to 4 days for full effect

Compare to the active ingredient in Nexium® 24 HR

24 Hour

CAPSULES

42

CAPSULES

ACTUAL SIZE

Three 14-day courses of treatment

**24 Hour**

Clinically Proven to  
Treat Frequent Heartburn

**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.



See New Warning Information



Esomeprazole Magnesium  
Delayed-Release Capsules, 20 mg

**ACID REDUCER**

Treats Frequent Heartburn

May take 1 to 4 days for full effect

Compare to the active ingredient in  
Nexium® 24 HR\*

**24 Hour**  
CAPSULES



ACTUAL SIZE

**42**  
CAPSULES

Three 14-day courses of treatment



0 72036 73344 3

**CODE AREA**

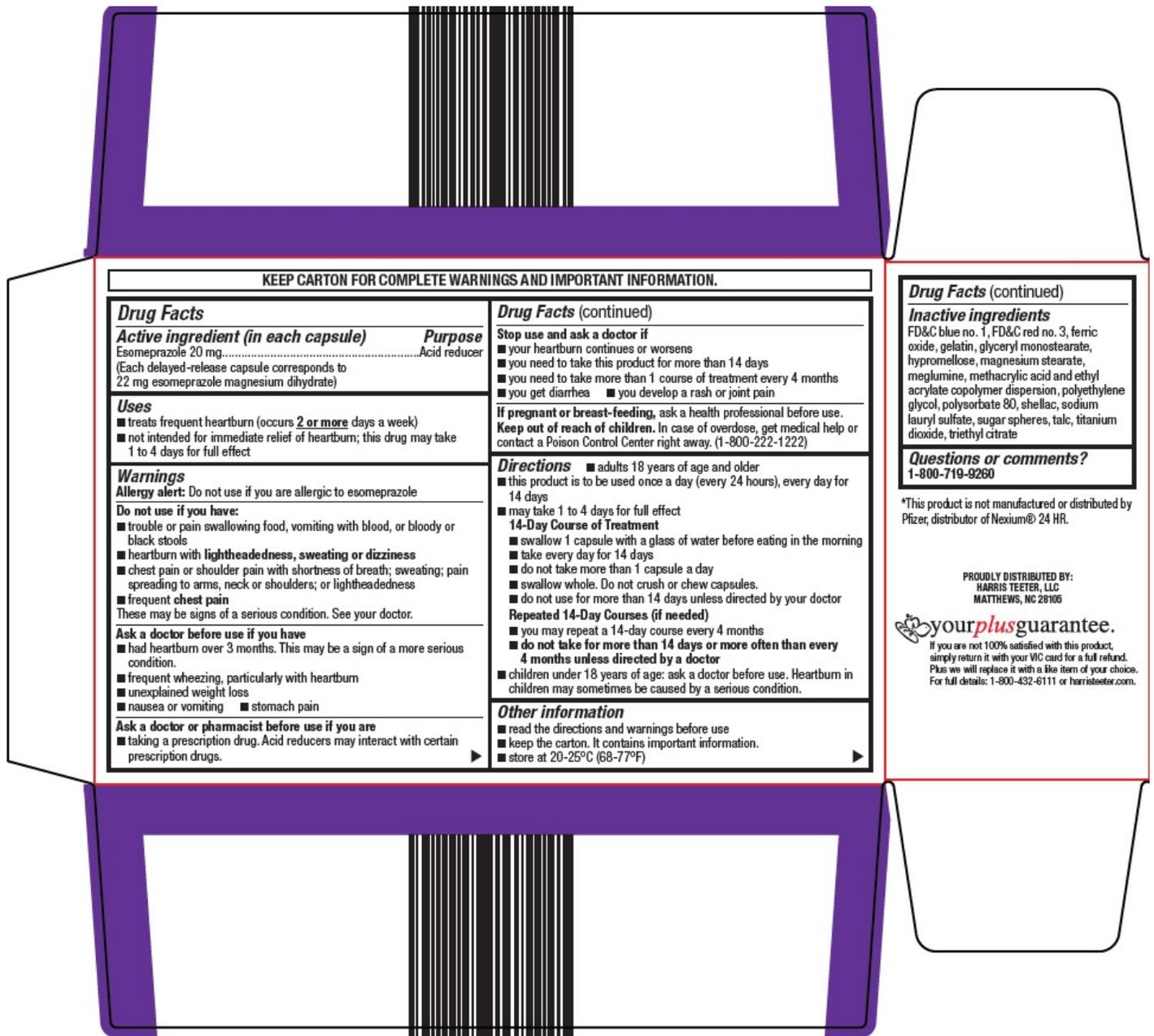
898D7 HT C3

3 Bottles inside

ACTUAL SIZE



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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 Esomeprazole 20 mg.....Acid reducer  
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  - frequent chest pain
- These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have**

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- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting    ■ stomach pain

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**Drug Facts (continued)**

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

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**Drug Facts (continued)**

**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

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

PROUDLY DISTRIBUTED BY:  
HARRIS TEETER, LLC  
MATTHEWS, NC 28105

your plus guarantee.

If you are not 100% satisfied with this product, simply return it with your VIC card for a full refund. Plus we will replace it with a like item of your choice. For full details: 1-800-432-6111 or harristeeter.com.

**HARRIS TEETER ACID REDUCER**

esomeprazole capsule, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69256-007
<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: 6HG8UB2MUY)	
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 (opaque)	Score	no score
Shape	CAPSULE (oblong)	Size	14mm
Flavor		Imprint Code	L898
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-007-01	1 in 1 CARTON	11/27/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69256-007-02	3 in 1 CARTON	03/01/2020	
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	11/27/2019	

**Labeler** - Harris Teeter, LLC (048463103)