

ESOMEPRAZOLE- esomeprazole capsule, delayed release
THE KROGER COMPANY

esomeprazole

Drug Facts

Active ingredient (in each capsule)

*Esomeprazole 20 mg (Each delayed-release capsule contains 22.3 mg esomeprazole magnesium trihydrate)

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
- Store at 20°C to 25°C (68°F to 7°F).
[See USP Controlled Room temperature.]
- keep the carton. It contains important information.

Inactive ingredients

FD & C blue no 1, FD & C red no 3, ferrosoferric oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion, mono and di glycerides, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sugar spheres (corn starch and sucrose), talc, titanium dioxide and triethyl citrate.

Questions?

1-800-632-6900

**DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202**

PRINCIPAL DISPLAY PANEL - 24 Capsule Bottle Carton

COMPARE TO the active ingredient of
NEXIUM[®] 24HR **See bottom panel

NDC 30142-989-28

Kroger[®]

Esomeprazole
Magnesium

Delayed-release
Capsules USP,
20 mg*

ACID REDUCER

actual size

OUR PHARMACIST
RECOMMENDED

Treats Frequent Heartburn!

24 HR

28 CAPSULES

Two 14-Day Courses of Treatment

May Take 1 to 4 Days for Full Effect



Esomeprazole Magnesium

Delayed-release
Capsules USP, 20 mg*
ACID REDUCER

Treats
Frequent
Heartburn!

24 HR

Drug Facts (continued)

Questions? 1-800-632-6900

TAMPER EVIDENT-FEATURES: Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or blue band around the center of each capsule is broken or missing.

2 BOTTLES INSIDE

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.

COMPARE TO the active ingredient of
NEXIUM® 24HR **See bottom panel

NDC 30142-989-28



Esomeprazole Magnesium

Delayed-release
Capsules USP,
20 mg*
ACID REDUCER



Treats Frequent Heartburn!

24 HR

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Two 14-Day Courses of Treatment
May Take 1 to 4 Days for Full Effect



** Nexium® is a registered trademark of AstraZeneca AB, Sweden, AstraZeneca AB is not affiliated with The Kroger Co. or this product.

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
QUALITY GUARANTEE
800-632-6900
www.kroger.com

R0920



Batch No.

Expiration Date:

NON VARNISH



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KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

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 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
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Ask a doctor before use if you have

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Drug Facts (continued)

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Drug Facts (continued)

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- you may repeat a 14-day course every 4 months
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Other information

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Inactive ingredients

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521 3702



ESOMEPRAZOLE

esomeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-989
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ESOMEPRAZOLE MAGNESIUM (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg
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Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	RG50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-989-28	2 in 1 CARTON	08/07/2020	
1	NDC:30 142-989-14	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	ANDA212866	08/07/2020	

Labeler - THE KROGER COMPANY (006999528)

Establishment

Name	Address	ID/FEI	Business Operations
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Ohm Laboratories Inc.

184769029

MANUFACTURE(30142-989)

Revised: 10/2020

THE KROGER COMPANY