

OMEPRAZOLE MAGNESIUM - omeprazole magnesium 20.6mg capsules capsule, delayed release

The Kroger Co.

Active ingredient(in each capsule)

Omeprazole delayed-release capsules 20 mg (equivalent to 20.6 mg omeprazole magnesium)

Purpose

Acid reducer

Use

- 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 omeprazole

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:

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask 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

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

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

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
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush capsules.

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. 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
- safety sealed: do not use if foil seal under cap printed with "sealed for your protection" or pink band around center of capsule are broken or missing.

Storage

- store at 20 – 25°C (68 – 77° F) and protect from moisture

Inactive ingredients

black iron oxide, dibasic calcium phosphate, gelatin, glyceryl monostearate, hypromellose 3 cps, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, methacrylic acid copolymer Type B, microcrystalline cellulose, polysorbate 80, potassium hydroxide, propylene glycol, red iron oxide, shellac, silicon dioxide, sodium lauryl sulphate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions?

call **1-800-632-6900**

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Carton label

Kroger

NDC 30142-012-52

Omeprazole

Delayed-Release Capsules 20 mg*

ACID REDUCER

Treats Frequent Heartburn

Occurring 2 or More Days a Week

One 14-Day Course of Treatment

14 SAFETY SEALED CAPSULES



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Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking:

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- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days 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

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Drug Facts (continued)

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- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients: black iron oxide, dibasic calcium phosphate, gelatin, glyceryl monostearate, hypromellose 3 cps, magnesium oxide, magnesium stearate, methacrylic acid copolymer Type B, microcrystalline cellulose, polysorbate 80, potassium hydroxide, propylene glycol, red iron oxide, silicon dioxide, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions? call 1-800-632-6000

**Prilosec OTC® is a registered trademark of AstraZeneca AB CORPORATION SWEDEN Södertälje, SWEDEN. AstraZeneca AB is not affiliated with The Kroger Co. or this product.

COMPARE TO the active ingredient of PRILosec OTC®

**See side panel

NDC 30142-012-52



Omeprazole

Delayed-Release Capsules 20 mg*

ACID REDUCER

Treats Frequent Heartburn Occurring 2 or More Days a Week

One 14-Day Course of Treatment



actual size

14 SAFETY SEALED CAPSULES

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

Made in India

QUALITY GUARANTEE

www.kroger.com

100% SIZE 12-digit UPC-A (Non-suppressor) For Position ONLY

0 41260 138082 2

LOT

EXP

Drug Facts

Active ingredient (in each capsule)	Purpose
Omeprazole delayed-release capsules 20 mg (equivalent to 20.6 mg omeprazole magnesium)	Acid reducer

Use

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- 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

Bottle label

Kroger

Treats Frequent Heartburn Occurring 2 or More Days a Week


Omeprazole

Delayed-Release Capsules 20 mg*

ACID REDUCER

ONE 14-Day Course of Treatment

14 SAFETY SEALED CAPSULES



Treats Frequent Heartburn Occurring 2 or More Days a Week

Omeprazole

Delayed-Release Capsules 20 mg*
ACID REDUCER
 ONE 14-Day Course of Treatment

14 SAFETY SEALED CAPSULES

IMPORTANT: This label does not contain full product information. See carton for complete information. Read the directions and warnings before use. Retain carton for reference.

Active ingredient Purpose (in each capsule)
 *Omeprazole delayed-release capsules 20 mg Acid (equivalent to 20.6 mg omeprazole magnesium).....reducer

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Questions? call 1-800-632-6900

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DISTRIBUTED BY THE KROGER CO.
 CINCINNATI, OHIO 45202
 QUALITY GUARANTEE
 www.kroger.com

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 EXP

OMEPRAZOLE MAGNESIUM

omeprazole magnesium 20.6mg capsules capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-0 12(NDC:55111-39 7)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (omeprazole - UNII:KG60484QX9)	omeprazole	20 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
Gelatin (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE 2208 (3 MPAS) (UNII: 9H4L916OBU)	
Magnesium Oxide (UNII: 3A3U0GI71G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)	
Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
RAW SUGAR (UNII: 8M707QY5GH)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Sodium Lauryl Sulfate (UNII: 368GB5141J)

Product Characteristics

Color	WHITE, PINK	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	OMP20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-012-52	1 in 1 CARTON	01/01/2016	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30 142-012-01	2 in 1 CARTON	01/01/2016	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:30 142-012-33	3 in 1 CARTON	01/01/2016	
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	ANDA078878	01/01/2016	

Labeler - The Kroger Co. (006999528)

Revised: 8/2018

The Kroger Co.