

**OMEPRAZOLE- omeprazole tablet, delayed release**  
**Kroger Company**

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**Kroger Co. Omeprazole Delayed Release Tablets 20 mg Drug Facts**

**Active ingredient (in each tablet)**

Omeprazole 20 mg

**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. 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.
- 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
- 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 (immune system medicine)
- 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
- 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 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush tablets

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

## **Inactive ingredients**

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

## **Questions or comments?**

1-800-632-6900

**Principal Display Panel**

Omeprazole

Delayed Release Tablets 20 mg

ACID REDUCER

Treats Frequent Heartburn!

Occurring 2 Or More Days A Week

14 TABLETS

One 14-Day Course of Treatment

actual size

**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

<p><b>Drug Facts (continued)</b></p> <p>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)</p> <p><b>Directions</b> ■ 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</p> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ swallow 1 tablet with a glass of water before eating in the morning</li> <li>■ take every day for 14 days</li> <li>■ do not take more than 1 tablet a day</li> <li>■ do not use for more than 14 days unless directed by your doctor</li> <li>■ swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> </ul> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a reflux condition.</p> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>■ read the directions and warnings before use</li> <li>■ keep the carton if contains important information</li> <li>■ store at 20-25°C (68-77°F) and protect from moisture</li> </ul> <p><b>Inactive Ingredients</b> carnaub wax, ferric oxide red, ferric oxide yellow, hypromellose, hydroxyethylcellulose, lactose monohydrate, mannitol, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate</p> <p><b>Questions or comments? 1-800-632-6900</b></p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient (in each tablet)</b> Omeprazole 20 mg.....Acid reducer</p> <p><b>Use</b> ■ 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</p> <p><b>Warnings</b></p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood or black stools. These may be signs of a serious condition. See your doctor.</p> <p>As a doctor before use if you have</p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with lightheadedness, sweating or dizziness</li> <li>■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</li> </ul> <p>As a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> <li>■ warfarin, clopidogrel or clostrazid (blood-thinning medicines)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ diazepam (anxiety medicine) ■ digoxin (heart medicine)</li> <li>■ tacrolimus or cyclosporine (immunosuppressant medicines)</li> <li>■ prescription antiretrovirals (medicines for HIV infection)</li> <li>■ methotrexate (anti-cancer medicine)</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you need to take more than 1 course of treatment every 4 months</li> <li>■ you get diarrhea</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use</b></p>
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NDC 30142-557-74

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



**Safety Feature - Do not use if printed tablet blister unit is open or torn.**

NDC 30142-557-74



# Omeprazole

Delayed Release Tablets 20 mg

**ACID REDUCER**

Treats Frequent Heartburn!  
Occurring 2 Or More Days A Week



**14**  
TABLETS

One 14-Day Course of Treatment

TABLETS

ONE 14-Day Course of Treatment

actual size

**OMEPRAZOLE**

omeprazole tablet, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30 142-557
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

**Inactive Ingredients**

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	

**Product Characteristics**

<b>Color</b>	BROWN	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	20
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-557-55	3 in 1 CARTON		
1		14 in 1 CARTON		

1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30 142-557-30	2 in 1 CARTON		
2		14 in 1 CARTON		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:30 142-557-74	14 in 1 CARTON		
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:30 142-557-01	1 in 1 CARTON		
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:30 142-557-02	2 in 1 CARTON		
5		14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:30 142-557-03	3 in 1 CARTON		
6		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
NDA	NDA022032	02/25/2008	

**Labeler** - Kroger Company (006999528)

Revised: 6/2015

Kroger Company