

**MEMBERS MARK OMEPRAZOLE- omeprazole tablet, delayed release  
Sam's West Inc**

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**Sam's West, Inc. 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
- 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**

- 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?**

**1-800-809-0469**

**Principal Display Panel**

Compare to Prilosec OTC®

VALUE PACK! 3-14 TABLET CARTONS

See current Drug Facts

24 HR

Omeprazole Delayed release tablets 20 mg

Acid reducer

actual size

Treats FREQUENT Heartburn!

42 Tablets

Three 14-day courses of treatment

May take 1 to 4 days for full effect

Compare to Prilosec OTC\*

NDC: 68196-91545



VALUE PACK! 3-14 TABLET CARTONS

See current Drug Facts

# Omeprazole

Delayed release tablets 20 mg  
Acid reducer



Treats **FREQUENT** Heartburn!

**42 Tablets**

Three 14-day courses of treatment  
May take 1 to 4 days for full effect

44783 ZV 012



<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet):</b> Omeprazole</p> <p><b>Purpose:</b> Acid reducer</p> <p><b>Use:</b> Use to treat frequent heartburn (more than once a week). It will relieve the burning pain of heartburn that may occur after a meal or at night.</p> <p><b>Warnings:</b> Always use it to reduce if you are allergic to omeprazole. Do not use if you are pregnant or breastfeeding. Do not use if you have had stomach pain, vomiting, or loss of appetite. Do not use if you have had stomach pain, vomiting, or loss of appetite. Do not use if you have had stomach pain, vomiting, or loss of appetite.</p> <p><b>Directions:</b> 14-Day Course: Take one tablet once a day (every 24 hours), one day for 14 days. 28-Day Course: Take one tablet once a day (every 24 hours), one day for 28 days. 42-Day Course: Take one tablet once a day (every 24 hours), one day for 42 days.</p> <p><b>Other information:</b> Keep out of reach of children. Store at room temperature (20° to 25°C).</p>	
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**100% MONEY BACK GUARANTEE**  
QUALITY AND PERFORMANCE

We would like to hear from you with any comments or suggestions. In the continental U.S. or Canada, you can call us at 1-800-809-0469 from 7:30 a.m. to 5:00 p.m. EST Monday - Friday.

**Tip for Managing Heartburn:** Do not lie down for 2 hours after eating. Do not eat spicy, fatty, or fried foods. Do not eat chocolate, caffeine, alcohol, or carbonated beverages. Do not wear tight clothing. Do not smoke. Do not drink alcohol. Do not take aspirin or other pain relievers. Do not take other medications without your doctor's advice.

**Other information:** Keep out of reach of children. Store at room temperature (20° to 25°C).

<b>MEMBERS MARK OMEPRAZOLE</b>			
omeprazole tablet, delayed release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-915
<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)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

**Product Characteristics**

Color	BROWN	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	20
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-915-55	3 in 1 CARTON	02/25/2008	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68196-915-74	14 in 1 CARTON	01/27/2016	09/01/2017
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:68196-915-03	3 in 1 CARTON	11/02/2016	02/01/2019
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68196-915-01	1 in 1 CARTON	11/02/2016	
4		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	

