## KIRKLAND SIGNATURE OMEPRAZOLE- omeprazole tablet, delayed release Costco Wholesale Company

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#### Costco Wholes ale Corp. Omeprazole Delayed Release Tablets 20 mg Drug Facts

#### Active ingredient (in each tablet)

Omeprazole 20 mg

#### **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 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-veast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

#### 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?

#### **Principal Display Panel**

OMEPRAZOLE Delayed Release Tablets 20 mg

Acid Reducer

Treats Frequent Heartburn!

occurring 2 or more days a week

Actual Size

# 14-Day courses of Treatment {Replace "#" with the number of courses of treatment in the package}





#### KIRKLAND SIGNATURE OMEPRAZOLE

omeprazole tablet, delayed release

# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:63981-915 Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OMEPRAZOLE (OMEPRAZOLE)	OMEPRAZOLE	20 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX		
FERRIC OXIDE RED		
FERRIC OXIDE YELLOW		
LACTO SE MO NO HYDRATE		
PROPYLENE GLYCOL		
SO DIUM LAURYL SULFATE		
SO DIUM STEARATE		
SO DIUM STEARYL FUMARATE		
TALC		
TITANIUM DIO XIDE		
TRIETHYL CITRATE		
MO NO ETHANO LAMINE		
TITANIUM DIO XIDE TRIETHYL CITRATE		

#### HYPROMELLOSES

Product Characteristics				
Color	BROWN	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	20	
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63981-915-55	3 in 1 CARTON			
1		14 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022032	02/27/2008	

### Labeler - Costco Wholesale Company (103391843)

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