# GOOD NEIGHBOR PHARMACY OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release

Amerisource Bergen

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### Amerisource Bergen Omeprazole Drug Facts

#### **Active ingredient (in each tablet)**

Omeprazole 20 mg

## **Purpose**

Acid reducer

#### Use

- treats frequent heartburn (occurs <u>2 or more</u> 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 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 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**

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- 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
- do not take this medicine with alcohol

#### **Repeated 14-Day Course (if needed)**

- you may repeat a 4-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
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F); keep product out of high heat and moisture

# **Inactive ingredients**

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

#### Questions or comments?

1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST

#### Package/Label Principal Display Panel

Compare to Prilosec OTC®

Omeprazole

delayed release orally disintegrating tablets 20 mg

Acid Reducer

Treats Frequent Heartburn!

Occurring 2 or More Days a Week

 $MELTech^{^{TM}}$ 

Melts In Your Mouth

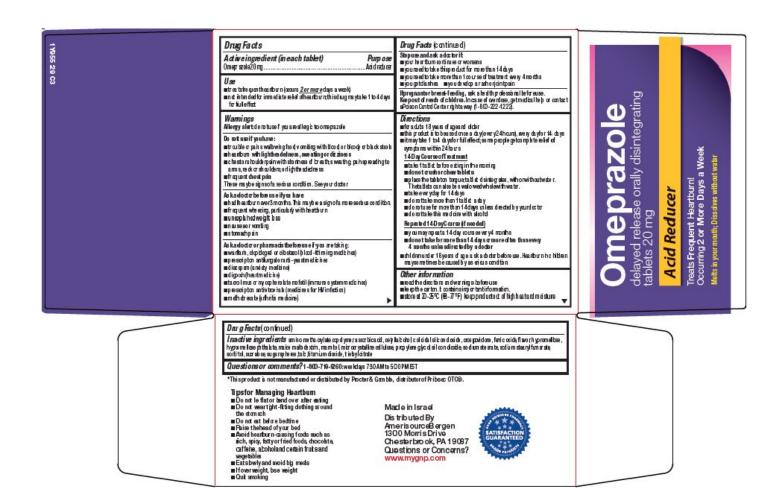
Melts in your mouth; Dissolves without water

Strawberry Flavor

actual size

42 Tablets | three 14-day courses of treatment





#### GOOD NEIGHBOR PHARMACY OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

Product Information	oduct Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-616
Route of Administration	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	
DIMETHYLAMINO ETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

MANNITOL (UNII: 30WL53L36A)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	RED (reddish)	Score	no score
Shape	ROUND	Size	9 mm
Flavor	STRAWBERRY	Imprint Code	20
Contains			

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:46122-616-04	3 in 1 CARTON	09/11/2019	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209400	09/11/2019	

# Labeler - Amerisource Bergen (007914906)

Revised: 1/2020 Amerisource Bergen