

**OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release**  
CVS Pharmacy

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**CVS Pharmacy, Inc. Omeprazole Delayed Release Orally Disintegrating 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 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**

- 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 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 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

Melts in your mouth

dissolves without water

DELAYED RELEASE ORALLY DISINTEGRATING TABLETS 20 mg

Actual Size

Acid Reducer

Treats Frequent Heartburn!

24 HR

Strawberry Flavor

42 TABLETS

Three 14-day courses of treatment

May take 1 to 4 days for full effect

MELTech™

Melts In Your Mouth

CVSHealth.

# Omeprazole

DELAYED RELEASE ORALLY  
DISINTEGRATING TABLETS 20 mg  
Acid Reducer  
Treats Frequent Heartburn!

Melts in  
your mouth

dissolves without water



Actual Size



CVSHealth.

Compare to Prilosec OTC<sup>SM</sup>

NDC 69842-791-55

# Omeprazole

DELAYED RELEASE ORALLY  
DISINTEGRATING TABLETS 20 mg  
Acid Reducer  
Treats Frequent Heartburn!

Melts in  
your mouth

dissolves without water



Actual Size



Strawberry Flavor



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



Melts In Your Mouth

17955-17 03



#255290

RELEASE NOTICE

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CVS.COM | 1-800-SHOP-CVS  
Made in Brazil  
V-10889

**Safety Feature—Do not use if printed blister wrapper is open or torn.**

### Drug Facts

**Active ingredient (per each tablet)** Omeprazole 20 mg. **Purpose** Acid reducer

**Use** Treats frequent heartburn (occurs 2 or more days a week) and is intended for immediate relief of these symptoms. It should be taken 1 to 4 days for full effect.

**Warnings** Always take with food. Do not use if you are allergic to omeprazole.

**Do not use if you have:** a history of severe allergic reactions to omeprazole or any of its ingredients; a history of severe allergic reactions to any of the ingredients listed under "Other ingredients"; or a history of severe allergic reactions to any of the ingredients listed under "Other ingredients". These may be signs of a severe allergic reaction. See your doctor.

**Ask a doctor or pharmacist before use if you are taking any prescription drugs, are taking or will be taking any other acid-reducing drugs, or are taking any other drugs that may interact with omeprazole.**

**Side effects and risks:** Omeprazole may cause dizziness, headache, nausea, and constipation. Omeprazole may cause diarrhea, which may be watery. Omeprazole may cause stomach pain. Omeprazole may cause constipation. Omeprazole may cause dry mouth. Omeprazole may cause fatigue. Omeprazole may cause back pain. Omeprazole may cause joint pain. Omeprazole may cause muscle pain. Omeprazole may cause weakness. Omeprazole may cause numbness or tingling. Omeprazole may cause blurred vision. Omeprazole may cause ringing in the ears. Omeprazole may cause changes in taste. Omeprazole may cause changes in smell. Omeprazole may cause changes in voice. Omeprazole may cause changes in breathing. Omeprazole may cause changes in heart rate. Omeprazole may cause changes in blood pressure. Omeprazole may cause changes in blood sugar. Omeprazole may cause changes in blood counts. Omeprazole may cause changes in kidney function. Omeprazole may cause changes in liver function. Omeprazole may cause changes in thyroid function. Omeprazole may cause changes in bone density. Omeprazole may cause changes in bone mineral density. Omeprazole may cause changes in bone mineral content. Omeprazole may cause changes in bone mineral density. Omeprazole may cause changes in bone mineral content. Omeprazole may cause changes in bone mineral density. Omeprazole may cause changes in bone mineral content.

**Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center at 1-800-232-2222.**

### Drug Facts (continued)

**Directions:** Take 1 tablet with food once daily. Take with water. Do not crush or chew. Do not take more than 1 tablet per day. Do not take more than 14 days of treatment. Do not take more than 42 tablets.

**Other information:** Omeprazole is a prescription drug. Omeprazole is not intended for use in children. Omeprazole is not intended for use in pregnant women. Omeprazole is not intended for use in nursing mothers. Omeprazole is not intended for use in people with liver disease. Omeprazole is not intended for use in people with kidney disease. Omeprazole is not intended for use in people with heart disease. Omeprazole is not intended for use in people with high blood pressure. Omeprazole is not intended for use in people with diabetes. Omeprazole is not intended for use in people with asthma. Omeprazole is not intended for use in people with allergies. Omeprazole is not intended for use in people with autoimmune diseases. Omeprazole is not intended for use in people with chronic conditions. Omeprazole is not intended for use in people with acute conditions. Omeprazole is not intended for use in people with severe conditions. Omeprazole is not intended for use in people with life-threatening conditions. Omeprazole is not intended for use in people with terminal conditions. Omeprazole is not intended for use in people with end-of-life conditions. Omeprazole is not intended for use in people with palliative care conditions. Omeprazole is not intended for use in people with hospice care conditions. Omeprazole is not intended for use in people with long-term care conditions. Omeprazole is not intended for use in people with nursing home conditions. Omeprazole is not intended for use in people with assisted living conditions. Omeprazole is not intended for use in people with residential care conditions. Omeprazole is not intended for use in people with community care conditions. Omeprazole is not intended for use in people with residential care conditions. Omeprazole is not intended for use in people with community care conditions.

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**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 alcohol, caffeine, chocolate, coffee, citrus fruits and vegetables.  
● Eat slowly and avoid big meals.  
● Avoid smoking and weight gain.  
● Quit smoking.

This product is not a treatment or a substitute for Prilosec OTC.

CVSHealth.

# Omeprazole

DELAYED RELEASE ORALLY  
DISINTEGRATING TABLETS 20 mg  
Acid Reducer  
Treats Frequent Heartburn!



# OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-791
<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
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (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 DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

<b>Color</b>	RED (reddish)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	20
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-791-55	3 in 1 CARTON	02/27/2018	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:69842-791-74	14 in 1 CARTON	03/01/2018	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NDA	NDA209400	02/27/2018		

**Labeler** - CVS Pharmacy (062312574)

Revised: 6/2019

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