

**OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release**  
**Rite Aid Corporation**

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**Rite Aid Corporation Omeprazole 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.
- omeprazole may cause severe skin reactions. Symptoms may include:
  - skin reddening
  - blisters
  - rash

If an allergic reaction occurs, stop use and seek medical help right away.

**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

- take the tablet immediately after opening individual blister. Do not store the tablet outside the blister pack for future use.

### **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**

TREATS FREQUENT HEARTBURN!

Compare to Prilosec OTC<sup>®</sup>

MELTech<sup>®</sup>

Melts In Your Mouth

OMEPRAZOLE

Delayed Release Orally Disintegrating Tablets, 20 mg

ACID REDUCER

ACTUAL SIZE

24 HR

STRAWBERRY FLAVOR

DISSOLVE TABS

MELTS IN YOUR MOUTH

DISSOLVES WITHOUT WATER

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

1Y955 83 C4

NDC 11822-1040-1

TREATS FREQUENT HEARTBURN!

Compare to Prilosec OTC®\*



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Tablets, 20 mg

ACID REDUCER

24HR



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STRAWBERRY  
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ACID REDUCER

Delayed Release Orally Disintegrating  
Tablets, 20 mg

# OMEPRAZOLE

### 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

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MADE IN ISRAEL

### SATISFACTION GUARANTEE

If you're not satisfied, we'll  
happily refund your money.





## OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-1040
<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)	

<b>CROSPROVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM STEARATE</b> (UNII: QU7E2XA9TG)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

<b>Product Characteristics</b>			
<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>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1040-1	3 in 1 CARTON	03/29/2018	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-1040-2	14 in 1 CARTON	03/13/2019	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209400	03/29/2018	

**Labeler** - Rite Aid Corporation (014578892)