# OMEPRAZOLE- omeprazole tablet, delayed release Rite Aid Corporation

-----

# **Rite Aid Corporation 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.
- 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 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, crush, or suck tablets.

# Repeated 14-Day Courses (if needed)

- you may repeat a14-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**

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

# Questions or comments? 1-800-719-9260

# Package/Label Principal Display Panel

TREATS FREQUENT HEARTBURN!

Compare to Prilosec OTC®

**OMEPRAZOLE** 

Delayed Release Tablets, 20 mg

**ACID REDUCER** 

**ACTUAL SIZE** 

24HR

WILDBERRY MINT COATED TABLET

SWALLOW - DO NOT CHEW

28 TABLETS

TWO 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

# **OMEPRAZOLE**

Delayed Release Tablets, 20 mg

ACID REDUCER

NDC 11822-0453-3

TREATS FREQUENT HEARTBURN!

Compare to Prilosec OTC®\*

#### 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

Safety Feature - Do not use if printed seal under cap is broken or missing.

DISTRIBUTED BY: RITE AID. 200 NEWBERRY COMMONS, ETTERS, PA 17319 www.riteaid.com MADE IN ISRAEL

# SATISFACTION GUARANTEE

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

# **OMEPRAZOLE**

Delayed Release Tablets, 20 mg

ACID REDUCER











TWO 14-DAY COURSES OF TREATMENT MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



401D6 83 C1



#### Drug Facts

Active ingredient (in each tablet) Purpose
Omeprazole 20 mg......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 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

#### Drug Facts (continued)

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
- vou 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, crush, or suck tablets.

#### Drug Facts (continued)

### 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 benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium launyl sulfate, sodium starch glycolate, sodium steerate, sodium steerate, sodium steerate, transcription in terrale, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?1-800-719-9260

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC\*.

2 BOTTLES INSIDE



# **OMEPRAZOLE**

omeprazole tablet, delayed release

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-0453

Route of Administration

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII: KG60484QX9)	OMEPRAZ OLE	20 mg	

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)		
MONOETHANOLAMINE (UNII: 5KV86114PT)		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM STEARATE (UNII: QU7E2XA9TG)		
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
TRIACETIN (UNII: XHX3C3X673)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics				
Color	PURPLE	Score	no score	
Shape	OVAL	Size	12mm	
Flavor	BERRY	Imprint Code	20	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 0453-1	3 in 1 CARTON	03/26/2015		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:11822- 0453-2	1 in 1 CARTON	03/20/2017		
2		14 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:11822- 0453-3	2 in 1 CARTON	07/27/2023		
3		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	03/26/2015	

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

Revised: 11/2023 Rite Aid Corporation