

**OMEPRAZOLE- omeprazole tablet, delayed release**  
**Praxis, LLC**

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**Publix Super Markets, Inc. 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 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 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 68-77°F (20-25°C) 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

**Package/Label Principal Display Panel**

P

omeprazole

DELAYED RELEASE TABLETS 20 mg

ACID REDUCER

24 HR

Treats Frequent Heartburn!

SWALLOW – DO NOT CHEW

14 TABLETS

ACTUAL SIZE

ONE 14-DAY COURSE OF TREATMENT

WILDBERRY MINT COATED TABLET

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

Compare to Prilosec OTC <sup>®</sup>



## OMEPRAZOLE

omeprazole tablet, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-323
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	

<b>CARMINIC ACID</b> (UNII: CID8Z8N95N)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>HYPROMELLOSE ACETATE SUCCINATE, UNSPECIFIED</b> (UNII: A7ZHS2RJ34)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>MONOETHANOLAMINE</b> (UNII: 5KV86114PT)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>SODIUM STEARATE</b> (UNII: QU7E2XA9TG)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	20
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-323-01	1 in 1 CARTON	07/11/2022	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-323-02	3 in 1 CARTON	07/01/2022	
2		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	07/01/2022	

**Labeler** - Praxis, LLC (016329513)

### Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-323) , label(59368-323) , pack(59368-323)

