

OMEPRAZOLE- omeprazole tablet, delayed release
Publix Super Markets Inc

Publix Super Markets, Inc. Omeprazole Delayed Release 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 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 or crush 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 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Principal Display Panel

omeprazole

DELAYED RELEASE TABLETS 20 mg

ACID REDUCER

24HR

Treats FREQUENT heartburn!

See current Drug Facts

ACTUAL SIZE

28 TABLETS

TWO 14-DAY COURSES OF TREATMENT

May take 1 to 4 days for full effect

Compare to Prilosec OTC®

omeprazole
 DELAYED RELEASE TABLETS 20 mg
 ACID REDUCER

Drug Facts (continued)

Directions
 If pregnant or breastfeeding, ask a health professional before use.
 Keep out of reach of children. In case of overdose, get medical help or contact Poisons Control (Canada) 1-800-222-2222.

Warnings
 Do not use if you have:
 - Allergy alert: Do not use if you are allergic to omeprazole.
 - Black stools
 - Trouble or pain swallowing food, vomiting with blood, or bloody or
 - stools or pain
 - Ask a doctor before use if you have:
 - Ask a doctor or pharmacist before use if you are taking a prescription
 - drug, liquid medicine, or vitamins with certain prescription drugs.
 - Spouse and sickle cell anemia.
 - You need to be more than 14 days
 - You need to be more than 14 days
 - You need to be more than 14 days

Use
 - at intended for immediate relief of heartburn; this may take 1 to
 - 4 days for full effect.

Purpose
 Omeprazole 20 mg Acid reducer

Active ingredient (in each tablet)

Other information
 - Keep the carton. It contains important information.
 - Store at 20-25°C (68-77°F) and protect from moisture
 - yellow, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate,
 - monohydroxyethylamine epiperazine glycol, and many others.
 - methyl citrate
 - This product is not manufactured or distributed by Procter & Gamble,
 - distributor of Prilosec OTC®.

Publix.
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 PUBLIC GUARANTEE:
 MADE IN ISRAEL
 1-888-267-3037
 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811 publix.com

Safety Features -
 Do not use if
 printed tablet
 blister unit is
 open or torn.



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 DELAYED RELEASE TABLETS 20 mg
 ACID REDUCER



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ACTUAL SIZE

24HR
Treats **FREQUENT** heartburn!

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28 TABLETS
TWO 14-DAY COURSES OF TREATMENT
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NDC 56062-915-30

*Compare to Prilosec OTC®

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-915
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-915-55	3 in 1 CARTON	05/14/2008	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-915-74	14 in 1 CARTON	05/12/2008	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:56062-915-30	2 in 1 CARTON	05/15/2008	
3		14 in 1 CARTON		
3		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	NDA022032	05/12/2008	

Labeler - Publix Super Markets Inc (006922009)

Revised: 4/2019

Publix Super Markets Inc