

OMEPRAZOLE- omeprazole tablet, delayed release
VALU MERCHANDISERS COMPANY

Omeprazole

Drug Facts

Active ingredient (in each tablet)

Omeprazole USP 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 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 to 25° C (68 to 77° F) and protect from moisture

Inactive ingredients

anhydrous lactose, hypromellose, hypromellose acetate succinate, iron oxide red, iron oxide yellow, lactose monohydrate, methyl cellulose, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate and titanium dioxide.

The imprinting ink contains ammonium hydroxide, black iron oxide, n-butyl alcohol,

propylene glycol and shellac.

Questions or Comments?

Call toll free 1-800-818-4555 weekdays.

**PROUDLY DISTRIBUTED BY:
ASSOCIATED WHOLESALE GROCERS, INC.
KANSAS CITY, KANSAS 66106**

PRINCIPAL DISPLAY PANEL - 20 mg Tablet Bottle Carton

Best
Choice®

Compare to
Prilosec OTC®*

See new warning information

ACID REDUCER

Omeprazole

DELAYED-RELEASE
TABLETS 20 mg

24
HOUR

14
TABLETS

Treats Frequent
Heartburn

May take 1 to 4 days
for full effect

SWALLOW-DO NOT CHEW

One 14-day course of treatment

PROUDLY DISTRIBUTED BY:
ASSOCIATED WHOLESALE GROCERS, INC.
KANSAS CITY, KANSAS 66106
PRODUCT OF INDIA
DNH/DRUGS/NH/138



Scan here for
more product information.
Call 1-844-292-1112
for more product information.

Glue - NO COATING

Drug Facts (continued)

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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 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.

1 BOTTLE INSIDE



Compare to
Prilosec OTC[®]

See new warning information

ACID REDUCER
Omeprazole
DELAYED-RELEASE
TABLETS 20 mg



Treats Frequent Heartburn

May take 1 to 4 days
for full effect

SWALLOW - DO NOT CHEW

20 **14**
TABLETS
One 14-day course of treatment

*All trademarks are property of their respective owners.
This product is not affiliated with the makers/owners of Prilosec OTC[®].

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Best Choice,
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NON VARNISH

No Coating Area

5 2 3 4 1 3 3

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 ■ 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 ▶

Drug Facts (continued)

■ unexplained weight loss
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No Coating Area

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-997
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE 12070923 (3 MPA.S) (UNII: 36BGF0E889)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
METHYLCELLULOSE (1500 MPA.S) (UNII: P0NTE48364)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIA (UNII: 5138Q19F1X)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	BROWN (brownish pink)	Score	no score
Shape	OVAL (biconvex)	Size	12mm
Flavor		Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-997-42	3 in 1 CARTON	07/21/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63941-997-14	1 in 1 CARTON	07/21/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA207891	07/20/2018	

Labeler - VALU MERCHANDISERS COMPANY (868703513)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(63941-997) , MANUFACTURE(63941-997)

Revised: 12/2023

VALU MERCHANDISERS COMPANY