

**MEMBERS MARK OMEPRAZOLE- omeprazole tablet, delayed release
Sam's West Inc**

Sam's West, 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 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?

1-800-809-0469

Package/Label Principal Display Panel

Member's Mark™

COMPARE TO PRILOSEC OTC®

VALUE PACK! THREE-14 TABLET BOTTLES

Omeprazole

DELAYED RELEASE TABLETS 20 mg | ACID REDUCER

Treats Frequent Heartburn! | 24 HR

WILDBERRY MINT COATED TABLET | SWALLOW - DO NOT CHEW

42 TABLETS | THREE 14-DAY COURSES OF TREATMENT.

ACTUAL SIZE | MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



MEMBERS MARK OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68196-700 |
| 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) | |
| CARMINIC ACID (UNII: CID8Z8N95N) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| HYPROMELLOSE ACETATE SUCCINATE, UNSPECIFIED (UNII: A7ZHS2R34) | |
| 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:68196-700-01 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 02/07/2024 | |
| 2 | NDC:68196-700- | 2 in 1 CARTON | 02/07/2024 | |

| | | | | |
|------------------------------|---------------------------|---|-----------------------------|---------------------------|
| 4 | 03 | 5 III 1 CARTON | 02/07/2024 | |
| 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 | 02/07/2024 | |

Labeler - Sam's West Inc (051957769)

Revised: 3/2024

Sam's West Inc