OMEPRAZOLE- omeprazole tablet, delayed release Family Dollar (FAMILY WELLNESS)

OMEPRAZOLE MAGNESIUM DELAYED-RELEASE TABLETS

Active ingredient (in each tablet)

Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium)

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 Ÿ
- 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 (1-800-222-1222) right away.

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

acetyl tributyl citrate, colloidal silicon dioxide, corn starch, croscarmellose sodium, dextrose, FD&C blue no. 2, FD&C red no.40, flavor, hydroxypropyl cellulose, hypromellose 2910, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 3350, polyethylene glycol 8000, polysorbate 80, polyvinyl alcohol, propylene glycol, sucralose, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

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

Principal display panel

†COMPARE TO THE ACTIVE INGREDIENT IN PRILOSEC OTC®

OMEPRAZOLE

Delayed-release tablets 20 mg

Acid reducer

TREAT FREQUENT HEARTBURN

- One 14-day course of treatment
- May take 1 to 4 days for full effect
- SWALLOW-DO NOT CHEW

COATED WITH WILDBERRY FLAVOR

TABLETS

†This product is not affiliated with, manufactured by or produced by the makers or owners of Prilosec OTC®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY: MIDWOOD BRANDS LLC, 500 VOLVO PKWY, CHESAPEAKE, VA 23320

Package label



FAMILY WELLNESS Acid Reducer Wildberry Flavor

OMEPRAZOLE omeprazole tablet, delayed release **Product Information HUMAN OTC DRUG** NDC:55319-219 **Product Type** Item Code (Source) ORAL **Route of Administration Active Ingredient/Active Moiety** Basis of **Ingredient Name** Strength Strength OMEPRAZOLE MAGNESIUM (UNII: 4260FE7XLK) (OMEPRAZOLE -OMEDDAZOLE

Inactive Ingredients	
Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics				
Color	purple (Light Purple)	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	0	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:55319- 219-14	1 in 1 BOX	02/28/2025		
1	14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA206582	02/28/2025			

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 2/2025 Family Dollar (FAMILY WELLNESS)