

OMEPRAZOLE- omeprazole tablet, delayed release
AMERISOURCEBERGEN DRUG CORPORATION

Omeprazole Delayed Release Tablets

Active ingredient(s)

Omeprazole USP, 20 mg

Purpose

Acid reducer

Use(s)

- 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 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

ammonia solution, ammonium hydroxide, carnauba wax, hypromellose acetate succinate, hypromellose, iron oxide black, lactose monohydrate, monoethanolamine, n-butyl alcohol, polyethylene glycol, polyvinyl alcohol, povidone, propylene glycol, red iron

oxide, sodium stearate, sodium starch glycolate, shellac glaze, sodium lauryl sulphate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide

Questions or comments?

call **1-888-375-3784**

Distributed By

AmerisourceBergen

1 West First Avenue

Conshohocken PA 19428

Made in India

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

NDC 46122-739-74

Treats Frequent Heartburn! •24 HR

Omeprazole

delayed-release tablets, 20 mg

Acid Reducer

14 Tablets
One 14-day Course of Treatment
May take 1 to 4 days for full effect

Safety Features: Do not use if printed seal (inner cap is broken or missing).

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts

Active ingredient Purpose
(in each tablet) Acid
Omeprazole USP, 20 mg.....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.▶

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1 West First Avenue
Conshohocken PA 19428
REV 01/23

LOT/EXP **15009 1069**

PEEL
HERE ▶

Drug Facts (continued)
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 ▶

Drug Facts (continued)
■ 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** ammonia solution, ammonium hydroxide, carnauba wax, hypromellose acetate succinate, hypromellose, iron oxide black, lactose monohydrate, monoethanolamine, n-butyl alcohol, polyethylene glycol, polyvinyl alcohol, povidone, propylene glycol, red iron oxide, sodium stearate, sodium starch glycolate, shellac glaze, sodium lauryl sulphate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide **Questions or comments?** call **1-888-375-3784**

Carton Label - 14 count

0 7 0 1 6 0 0 9 1



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 redness • 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 arm, neck or shoulder, 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 8 months. This may be a sign of a more serious condition.
 • frequent indigestion, 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

Drug Facts (continued)
 • 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 Poison Control Center right away (1-800-222-1222).

Directions
 • for adults 18 years of age and older
 • the 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 1-2 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 crush 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 in original container for information.
 • store at 20 to 25°C (68 to 77°F) and protect from moisture

Inactive ingredients
 ammonium sulfate, ammonium hydroxide, carnauba wax, hypromellose succinate, hypromellose, iron oxide black, lactose monohydrate, microcapsules, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, potassium glycol, red iron oxide, sodium citrate, sodium methacrylate, stearic acid, sodium lauryl sulfate, sodium stearoyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide

Questions or comments? call 1-888-373-3784

1 5 0 0 9 1 0 7 0

SAFETY FEATURE: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING!

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

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®. Prilosec OTC® is a registered trademark of AmZex/Amc AB.

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 1 West First Avenue
 Conshohocken, PA 19428
 Questions or Concerns?
 www.mg-jco.com

Made in India REV 01/23

GOOD NEIGHBOR PHARMACY® NDC 46122-739-74

Omeprazole
 delayed-release tablets, 20 mg
Acid Reducer
 1 BOTTLE INSIDE

Compare to Prilosec OTC® active ingredient*

GOOD NEIGHBOR PHARMACY® NDC 46122-739-74

Omeprazole
 delayed-release tablets, 20 mg
Acid Reducer
 °24 HR
 Treats Frequent Heartburn!

14 Tablets One 14-day Course of Treatment May take 1 to 4 days for full effect

LOT EXP

ABG 1 0275935



0 8770143510 2

1 BOTTLE INSIDE 14 TABLETS TOTAL



NDC 46122-739-74

Treats Frequent Heartburn
Omeprazole
 delayed-release tablets, 20 mg
Acid Reducer
 14 Tablets One 14-day Course of Treatment May take 1 to 4 days for full effect

actual size

| OMEPRAZOLE | | | |
|--|----------------|--------------------|---------------|
| omeprazole tablet, delayed release | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46122-739 |
| 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 | |
| AMMONIA (UNII: 5138Q19F1X) | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | |
| HYPROMELLOSE ACETATE SUCCINATE 06081224 (3 MM2/S) (UNII: 6N003M473W) | | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | | |
| MONOETHANOLAMINE (UNII: 5KV86114PT) | | | |
| BUTYL ALCOHOL (UNII: 8PJ61P6TS3) | | | |
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | | | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | | | |
| POVIDONE (UNII: FZ 989GH94E) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | |

| | |
|---|--|
| SODIUM STEARATE (UNII: QU7E2XA9TG) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| SHELLAC (UNII: 46N107B71O) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|----------|
| Color | BROWN (brownish pink) | Score | no score |
| Shape | CAPSULE | Size | 12mm |
| Flavor | | Imprint Code | O20 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:46122-739-74 | 1 in 1 CARTON | 08/30/2023 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:46122-739-03 | 2 in 1 CARTON | 08/30/2023 | |
| 2 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:46122-739-04 | 3 in 1 CARTON | 08/30/2023 | |
| 3 | | 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA207740 | 11/06/2018 | |

Labeler - AMERISOURCEBERGEN DRUG CORPORATION (007914906)

Revised: 8/2023

AMERISOURCEBERGEN DRUG CORPORATION