

**OMEPRAZOLE- omeprazole tablet, delayed release**  
**AMERISOURCEBERGEN DRUG CORPORATION**

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**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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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:  
 Omeprazole may cause severe skin reactions. Symptoms may include: skin redness, blisters, or rashes.  
 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 abdomen, or lightheadedness  
 frequent chest pain

**There 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 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:  
 Take 1 tablet once a day (every 24 hours) every day for 14 days.  
 If you take 1 to 4 days for full effect, some people get complete relief of symptoms within 12 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.

**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  
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 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

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GOOD NEIGHBOR PHARMACY

Compare to Prilosec OTC® active ingredient\*

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)			

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

### Product Characteristics

<b>Color</b>	BROWN (brownish pink)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	O20
<b>Contains</b>			

### 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: 11/2024

AMERISOURCEBERGEN DRUG CORPORATION