

**OMEPRAZOLE- omeprazole tablet, delayed release**  
**BluePoint Laboratories**

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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**

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

Manufactured for:

**Dr. Reddy's Laboratories, Inc.**

Princeton, NJ 08540

For BluePoint Laboratories

**Made in India**

Revised:12/22

**PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION**



**Drug Facts (continued)**

- 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

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**Drug Facts (continued)**

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**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, camouba 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 1-888-375-5784

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**1 BOTTLE INSIDE**

Manufactured for:  
Dr. Reddy's Laboratories, Inc.  
Princeton, NJ 08540  
For BluePoint Laboratories

Made in India

REV 12/22

**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**

NDC 68001-441-98

Compare to the active ingredient in Prilosec OTC®



Treats Frequent Heartburn!

**Omeprazole**  
Delayed-Release Tablets

**20 mg**

Acid Reducer

May take 1 to 4 days for full effect

One 14-Day Course of Treatment



14 Tablets



LOT

EXP

**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 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 ▶



NDC 68001-441-05

Relieves Frequent Heartburn!

**Omeprazole**

Delayed-Release Tablets

**20 mg**

Acid Reducer

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

**BluePoint**  
LABORATORIES

14 Tablets

**Safety Features: Do not use if the tablet seal is broken or if the blister pack is damaged.**

**KEEP CALM FOR DO COMPLETE TREATMENT OF HEARTBURN WITH THIS PRESCRIPTION!**

**Drug Facts**

**Purpose**  
Acid Reducer

**Active Ingredient**  
(In each tablet) Omeprazole USP, 20 mg, acid reducer

**Uses** ■ treats frequent heartburn (occurs 2 or more days a week)

**Warnings** ■ not intended for immediate relief of heartburn, the drug may take 1 to 4 days for full effect. **Warm Ups**

**Allergy alert:** ■ do not use if you are allergic to omeprazole

**Other information:** ■ omeprazole may cause severe skin reactions. Symptoms may include: ■ skin rash ■ 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 stiffness of joints ■ sweating, pain in spreading to arms, neck or shoulders, or **lightheadedness** ■ frequent **chest pain** These may be signs of a serious condition. See your doctor.

**Directions:** ■ For adults 18 years of age and older use 1 tablet once a day (every 24 hours), every day for 14 days

**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 use 1 tablet once a day (every 24 hours), every day for 14 days

Made in India  
Rev. 04/2013  
LOT:EXP 15 0091735

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**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

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**Drug Facts (continued)**

■ It may take 1 to 4 days for full effect; some people get complete relief or symptoms within 24 hours

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■ 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

■ if swallow whole. Do not chew or crush tablets. **Repeat 14-Day Course (if needed)** ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than 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:** ammonium hydroxide, cerulea wax, hypromellose acetate succinate, hypromellose, iron oxide black, lactose monohydrate, monomethacrylate, n-butyl alcohol, polyethylene glycol, polyvinyl alcohol, powder, propylene glycol, red iron oxide, sodium lauryl sulfate, sodium starch glycolate, small amount of sodium lauryl sulfate, sodium stearoyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide. **Questions or comments?** call 1-888-375-3784

<b>OMEPRAZOLE</b>			
omeprazole tablet, delayed release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-441
<b>Route of Administration</b>	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)	
FERROSFERRIC 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: FZ989GH94E)	
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)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

**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:68001-441-55	14 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	06/20/2020
2	NDC:68001-441-98	1 in 1 CARTON	06/19/2020	
2	NDC:68001-441-55	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68001-441-39	2 in 1 CARTON	06/19/2020	
	NDC:68001-441-55	14 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:68001-441-55	14 in 1 BOTTLE; Type 0: Not a Combination Product	
4	NDC:68001-441-40	3 in 1 CARTON	06/19/2020
4	NDC:68001-441-55	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	06/19/2020	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (SEZ UNIT)		860037244	analysis(68001-441) , manufacture(68001-441)

Revised: 9/2023

BluePoint Laboratories