

**OMEPRAZOLE- omeprazole tablet, delayed release**  
**Dr. Reddys Laboratories Inc**

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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:

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

Princeton, NJ 08540

**Made in India**

## PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

Container Carton 14's Pack

HealthCare  Aisle NDC 43598-841-52

Treats **FREQUENT** Heartburn!

# Omeprazole

Delayed-Release Tablets  
20 mg  
Acid Reducer

24

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 under cap is broken or missing.

**KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.**

**Drug Facts**

Active Ingredient	Purpose
Omeprazole USP, 20 mg.....reducer	Acid

**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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Made in India  
LOT/EXP 150091756  
REV 12/22

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

## PRINCIPAL DISPLAY PANEL

Bottle Carton:14 ct



1 5 0 0 9 1 7 5 4

### 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**

HealthCare  Aisle

NDC 43598-841-52

Compare to the active ingredient in Prilosec OTC<sup>®</sup>

Treats **FREQUENT** Heartburn!

# Omeprazole

## Delayed-Release Tablets

### 20 mg

Acid Reducer




actual size

### Drug Facts

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

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- frequent wheezing, particularly with heartburn
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### Drug Facts (continued)

- nausea or vomiting
- stomach pain

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**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months ▶

### Drug Facts (continued)

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**Questions or comments?**  
call 1-888-375-3784

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

**1 BOTTLE INSIDE**

Distributed by: Dr. Reddy's Laboratories, Inc.  
Princeton, NJ 08540

Made in India Revised: 12/22

HealthCare  Aisle

NDC 43598-841-52

Compare to the active ingredient in Prilosec OTC<sup>®</sup>

Treats **FREQUENT** Heartburn!

# Omeprazole

## Delayed-Release Tablets

### 20 mg

Acid Reducer




actual size

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

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- frequent wheezing, particularly with heartburn
- unexplained weight loss



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Lot

Exp

## OMEPRAZOLE

omeprazole tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-841
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>OMEPRAZOLE</b> (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSE ACETATE SUCCINATE 06081224 (3 MM2/S)</b> (UNII: 6N003M473W)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MONOETHANOLAMINE</b> (UNII: 5KV86114PT)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>Polyethylene Glycol 3350</b> (UNII: G2M7P15E5P)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SODIUM STEARATE</b> (UNII: QU7E2XA9TG)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<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:43598-841-52	1 in 1 CARTON	10/01/2020	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-841-42	3 in 1 CARTON	10/01/2020	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA207740	10/01/2020	

**Labeler** - Dr. Reddys Laboratories Inc (802315887)

Revised: 11/2024

Dr. Reddys Laboratories Inc