

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

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

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

Revised: 0419

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

Container carton: 14's pack



Drug Facts (continued)

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Drug Facts (continued)

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Other Information

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- 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, hydroxyethylcellulose 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?

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

1 BOTTLE INSIDE

Distributed by: Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540
Made in India Revised: 0419

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

Dr. Reddy's NDC 43598-286-52

Compare to the active ingredient in Prilosec OTC®**

Treats Frequent Heartburn!

Omeprazole

Delayed-Release Tablets
20 mg

ACID REDUCER

24 HR

14 Tablets

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

Drug Facts

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

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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. ▶



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Lot
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Blister Carton: 14's pack

Drugs Facts (continued)

- Keep the carton. It contains important information.
- Store at 20 to 25°C (68 to 77°F) and protect from moisture.

Drugs Facts (continued)

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.

NDC 43598-286-74

Treats **Frequent Heartburn!**
Occurring **2 Or More Days a Week**

Omeprazole

Delayed-Release Tablets


20 mg

Acid Reducer

14 Tablets (1 x 14 unit-dose)

14 TABLETS

ONE 14-DAY COURSE OF TREATMENT



Dr.Reddy's

Drugs Facts (continued)

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

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- 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:

- warfarin, dopidogrel or clocastazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Drugs Facts (continued)

Stop use and ask a doctor if:

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- you get diarrhea
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Directions

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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

Safety Feature - DO NOT USE IF PRINTED TABLET BLISTER UNIT IS OPEN OR TORN.

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

Labeling Format Information:

Fonts: DRL circular condensed light, bold, black

Drug Facts: 12 pt

Header: 8 pt

Subheader: 6pt

Body Text: 6 pt

Drugs Facts (continued): 10 pt

Leading: 7 pt

Bullets: 5 pt

Barlines: 2.5 pt

Hairlines: 0.5 pt

Color Key:

- 294 C
- 2091 C
- Black
- 158C

Fonts: DRL Circular

Drugs Facts (continued)

propylene glycol, red iron oxide, sodium stearate, sodium starch glycolate, silica gel, sodium lauryl sulphate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide

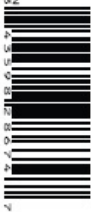
Questions or comments?
call 1-888-378-3784

Drugs Facts (continued)

Manufactured by: Dr. Reddy's Laboratories Limited, Srikalahasti - 523 402 INDIA

Lot

Exp



OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-286
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)	
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)	
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:43598-286-52	14 in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2018	
2	NDC:43598-286-27	2 in 1 CARTON	11/06/2018	
2	NDC:43598-286-52	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-286-33	3 in 1 CARTON	11/06/2018	
3	NDC:43598-286-52	14 in 1 BOTTLE; Type 0: Not a Combination Product		

4	NDC:43598-286-74	1 in 1 CARTON	11/06/2018	
4		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:43598-286-25	2 in 1 CARTON	11/06/2018	
5		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:43598-286-37	3 in 1 CARTON	11/06/2018	
6		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:43598-286-32	2 in 1 CARTON	11/06/2018	
7	NDC:43598-286-70	7 in 1 BLISTER PACK; 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 - Dr. Reddys Laboratories Inc (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (SEZ UNIT)		860037244	analysis(43598-286) , manufacture(43598-286)

Revised: 4/2019

Dr. Reddys Laboratories Inc