

OMEPRAZOLE- omeprazole tablet, delayed release
Walgreens Company

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

0 2 8 8 0 0 0 1



Drug Facts
(in each tablet)

Active ingredient
Omeprazole USP, 20 mg

Purpose
Acid reducer

Warnings

Other information

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

3 BOTTLES INSIDE

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
- Eliminate, lose weight
- Quit smoking

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

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT
MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

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DEERFIELD, IL 60015
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ITEM 610475 W00000-0000-0
11917 21326 6

LOT _____
EXP _____

3 BOTTLES INSIDE

Treats frequent heartburn!
NDC 0383-1607-42

3 BOTTLES INSIDE
42 TABLETS TOTAL

Treats frequent heartburn!
NDC 0383-1607-42

42 TABLETS

ONE 14-DAY COURSE OF TREATMENT
MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

LOT _____
EXP _____

1 0 0 9 3 9 7 0



Treats frequent heartburn!

Walgreens

Omeprazole
 DELAYED-RELEASE TABLETS 20 mg /
 ACID REDUCER

14 TABLETS 24 HOUR

ONE 14-DAY COURSE OF TREATMENT
 MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

NDC:0363-1607-14

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**
 (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

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 ©2023 Walgreen Co. MADE IN INDIA
 Walgreens® Protonix® is recommended. Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.
 ITEM 610121 W00000-0000-0 W30R091922-F REV-024

LOT/EXP 15 0094 190

PEEL HERE

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

OMEPRAZOLE			
omeprazole tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1607(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)
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: 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:0363-1607-14	14 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2020	
2	NDC:0363-1607-28	2 in 1 CARTON	01/15/2020	
2	NDC:0363-1607-14	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-1607-42	3 in 1 CARTON	01/15/2020	
3	NDC:0363-1607-14	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	01/15/2020	

Labeler - Walgreens Company (008965063)

Revised: 11/2024

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