

OMEPRAZOLE- omeprazole capsule, delayed release

Rite Aid

Drug Facts

Active ingredient (in each capsule)

*Omeprazole delayed-release capsule 20 mg (equivalent to 20.6 mg omeprazole magnesium, USP)

Purpose

Acid reducer

Keep Out of Reach of Children

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

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 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
- 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 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush capsules.

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 Safety Information

- read the directions and warnings before use
- keep the carton. It contains important information.
- Store at 20-25°C (68-77°F). [See USP controlled room temperature]. Protect from moisture

Inactive Ingredients

FD&C blue #1, FD&C red #40, ferrosoferric oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium stearate, methacrylic acid copolymer, mono and diglycerides, polyethylene glycol 6000, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sodium stearyl fumarate, sugar spheres (starch and sucrose), talc, titanium dioxide and triethyl citrate

Questions?

Call toll-free Monday to Friday 8:30 am to 5 pm EST at **1800-406-7984**

PRINCIPAL DISPLAY PANEL - 42 Capsule Bottle Carton

NDC 11822-0061-4

TREATS FREQUENT HEARTBURN

Compare to the active ingredient of Prilosec OTC^{®†}

OMEPRazole

Delayed-release Capsules 20 mg*

ACID REDUCER

Mini Cap 40% Smaller Capsule

24 HR

ACTUAL SIZE

42

CAPSULES

THREE 14-DAY COURSES OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

TRIPLE PACK 3 X 14 COUNT BOTTLE INSIDE

OMEPRAZOLE

Delayed-release Capsules 20 mg*

ACID REDUCER

Drug Facts (continued)

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EST at 1-800-406-7984

TAMPER-EVIDENT FEATURES:

Do not use if foil seal under cap
imprinted with "sealed for your
protection" or transparent band
around center of capsule are
missing, torn or broken.

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R1021

DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE,
CAMP HILL, PA 17011
www.riteaid.com

SATISFACTION GUARANTEE

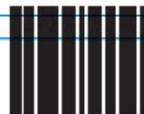
If you're not satisfied, we'll
happily refund your money.



0 11822 78192 3

Batch No.

Expiration Date:



5225851

Tips for Managing Heartburn

- Do not lie flat or bend over
after eating
- Do not wear tight-fitting
clothing around the stomach

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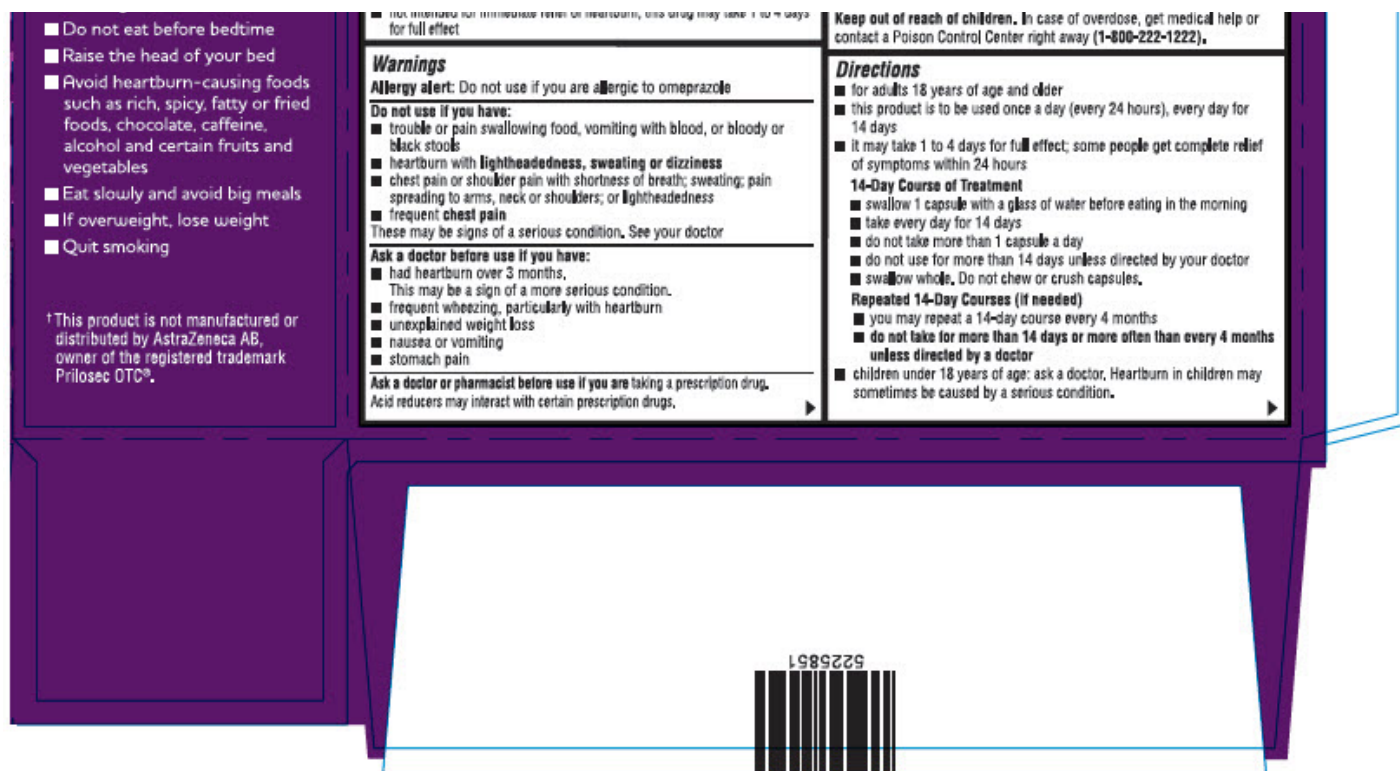
Purpose

Drug Facts (continued)

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- you get diarrhea
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OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0061
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20.6 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2208 (100 MPAS) (UNII: B1QE5P712K)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SHELLAC (UNII: 46N107B71O)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	RG49
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0061-4	3 in 1 CARTON	08/05/2020	
1	NDC:11822-0061-1	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	ANDA210593	08/05/2020	

Labeler - Rite Aid (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(11822-0061)

Revised: 3/2022

Rite Aid