

OMEPRAZOLE- omeprazole tablet, delayed release
CHAIN DRUG MARKETING ASSOCIATION, INC.

Omeprazole Delayed-Release Tablets, 20 mg/acid reducer

Active ingredient (in each tablet)

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

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 reddening • blisters • rashIf an allergy 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 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.

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

colloidal silicon dioxide, crospovidone, glyceryl monostearate, hypromellose, hydroxypropyl cellulose, iron oxide red, magnesium stearate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, silicified microcrystalline cellulose, sodium hydroxide, sodium lauryl sulphate, starlac (contains lactose monohydrate and corn starch), sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

Questions?

1-888-375-3784

PRINCIPAL DISPLAY PANEL

NDC 83324-011-42

See Current Drug Facts

Compare to Prilosec OTC [®]*

**Omeprazole
Delayed-Release Tablets
20 mg**

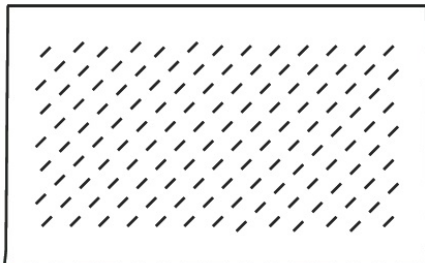
Acid Reducer

*Treats **FREQUENT** Heartburn!
Occuring **2 Or More Days A Week***

24 HR

*One 14-day course of treatment
May take 1 to 4 days for full effect*

14 TABLETS



NDC 83324-011-14

*** Compare to the Active Ingredient in Prilosec OTC***

Omeprazole

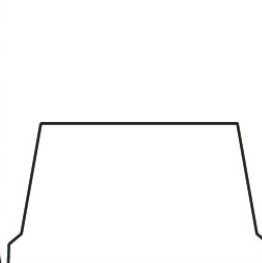
Delayed-Release Tablets, 20 mg

Frequent Heartburn Relief

24 HR Acid Reducer

actual size

14 Tablets
One 14-Day Course of Treatment
May Take 1 to 4 Days for Full Effect



Drug Facts

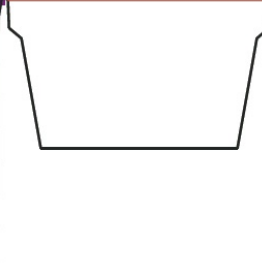
Active ingredient (in each tablet) Purpose
Omeprazole delayed-release tablet, 20 mg (equivalent to 20.6 mg omeprazole magnesium USP).....Acid reducer

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Ask a doctor before use if you have: ▶



Iss: 05/2023
Made in India.

This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC.

Safety Search: do not use if carton is opened or if printed lot number seal on the bottle is torn or missing.

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

Drug Facts (continued)

- 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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14-Day Course of Treatment

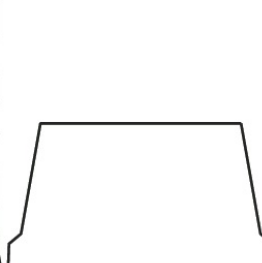
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6 355315 99778 3 2077299

Unvarnished Area for Batch coding
62x23 mm



Drug Facts (continued)

- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

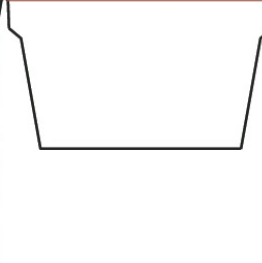
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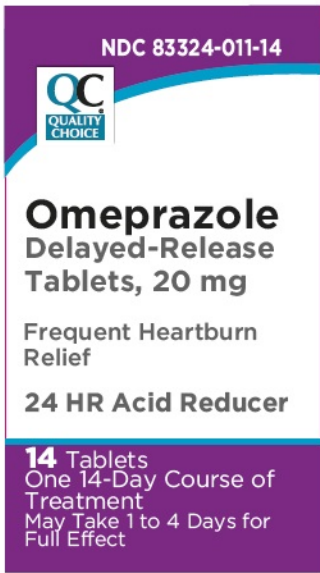
Inactive ingredients colloidal silicon dioxide, croscovidone, glyceryl monostearate, hypromellose, hydroxypropyl cellulose, iron oxide red, magnesium stearate, methacrylic acid copolymer, polyethylene glycol, polyorbate 80, silicified microcrystalline cellulose, sodium hydroxide, sodium lauryl sulphate, stearic (contains lactose monohydrate and corn starch), sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

Questions? 1-888-375-3784

Mfg. Lic. No.: 22/RVAP/2001/F/R

Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

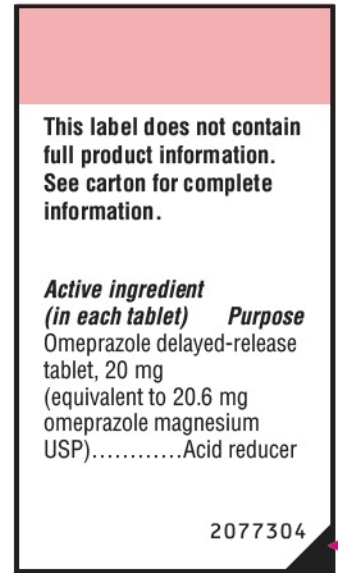




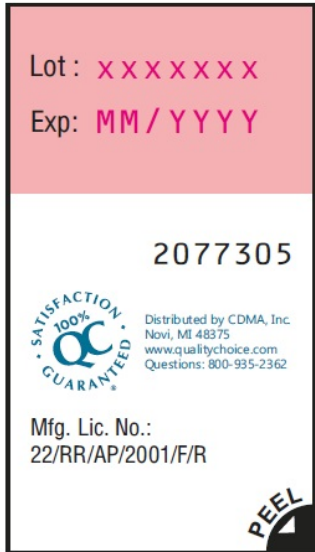
Layer 1 (Front)



Layer 1 (Back)



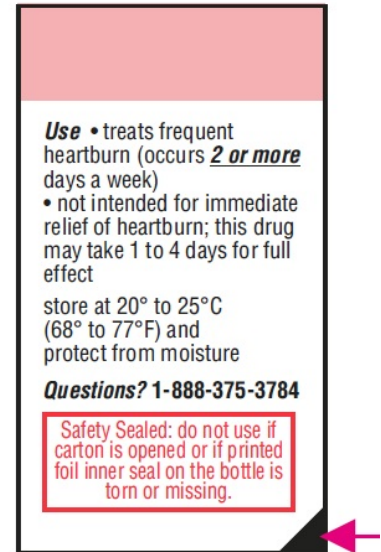
Layer 2 (Front)



Label 2 (front)



Label 2 (Front Back)



Label 2 (2nd Layer)

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-011
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPROVIDONE (UNII: 68401960MK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
SUCROSE (UNII: C151H8M554)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	H;09
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-011-14	1 in 1 CARTON	05/10/2024	
1		14 in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:83324-011-42	3 in 1 CARTON	05/10/2024	
2		14 in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211732	05/10/2024	

Labeler - CHAIN DRUG MARKETING ASSOCIATION, INC. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit III		676162024	manufacture(83324-011)

Revised: 4/2024

CHAIN DRUG MARKETING ASSOCIATION, INC.