

OMEPRAZOLE - omeprazole capsule, delayed release
Aurohealth LLC

Drug Facts

Active ingredient (in each capsule)

Omeprazole delayed-release capsules, USP 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 • 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 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 information

- **each capsule contains:** calcium 110 mg
- 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
- FDA approved dissolution test specifications differ from USP.

Inactive ingredients

black iron oxide, colloidal silicon dioxide, dibasic calcium phosphate anhydrous, gelatin, hypromellose, iron oxide red, macrogol, magnesium oxide, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, methacrylic acid and methyl methacrylate copolymer, microcrystalline cellulose, mono and di-glycerides, polysorbate 80, polyvinyl alcohol-part. hydrolyzed, potassium hydroxide, shellac, sodium lauryl sulphate, sugar spheres [liquid glucose, starch (maize), sucrose], talc, titanium dioxide, triethyl citrate.

Questions?

Call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

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

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsules Bottle)

**AUROHEALTH
NDC 58602-837-05**

See current Drug Facts

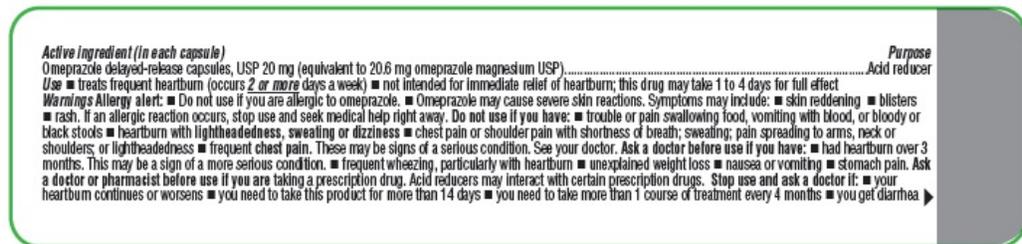
Omeprazole
Delayed-Release Capsules, USP
20 mg/Acid Reducer
*Treats **Frequent** Heartburn!*
24 HR
14 Capsules
One 14-Day Course of Treatment
May take 1 to 4 days for full effect

Top Ply



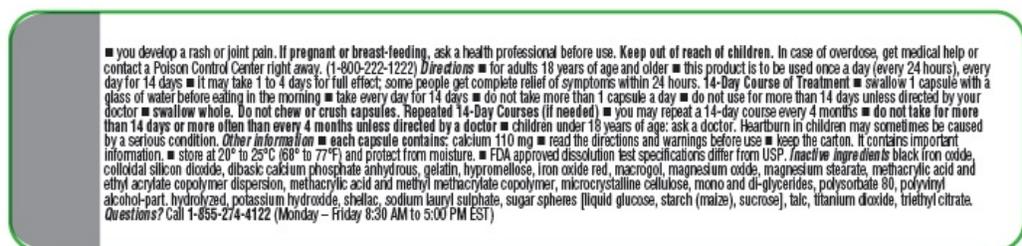
* Lot: XXXXXXXXX
 EXP: MM/YYYY
 Prefix & Variables of Lot, EXP shall be printed online during packing.

Top Ply (Page #1)



Back of Top Ply (Page #2)

Bottom Ply



Base (Page #3)

NDC 58602-837-05

See current Drug Facts

*Compare to the active ingredient in Prilosec OTC®

**Omeprazole
Delayed-Release
Capsules, USP
20 mg/Acid Reducer
Treats Frequent Heartburn!
24 HR**

OZM 20

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



OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-837
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PINK (light pinkish red cap) , WHITE (White to off white body)	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	OZ M;20

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-837-05	1 in 1 CARTON	04/28/2023	
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	ANDA213201	04/28/2023	

Labeler - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-837) , MANUFACTURE(58602-837)

Revised: 2/2024

Aurohealth LLC