

OMEPRAZOLE- omeprazole tablet, delayed release
GERICARE PHARMACEUTICALS

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**

PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION

Drug Facts Active ingredient (in each tablet) Omeprazole USP, 20 mg 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 Always 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 light-headedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or light-headedness ■ 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 6 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 dizziness ■ you develop a rash or joint pain		Drug Facts (continued) 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 (1-800-232-1222). 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 or unless you feel better Repeat 14-Day Course (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 20-25°C (68-77°F) and protect from moisture Inactive ingredients amoxicillin hydrochloride, 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 starch glycolate, shellac, glass, sodium lauryl sulfate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate, yellow iron oxide Questions or comments? call 1-888-375-3784	
Safety Feature: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN 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		GERI CARE® Treats Frequent Heartburn! May take 1 to 4 days for full effect Omeprazole Delayed-Release Tablets, 20 mg Acid Reducer 24 HR 42 Tablets Three 14-Day Courses of Treatment 3 BOTTLES INSIDE NDC 57896-960-42 Actual Size	

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-960
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: 46N107B710)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4U1)		
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:57896-960-42	3 in 1 CARTON	11/06/2018	
1	NDC:57896-960-14	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	11/06/2018	

Labeler - GERICARE PHARMACEUTICALS (611196254)

Registrant - GERICARE PHARMACEUTICALS (611196254)

Revised: 12/2019

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