

ZEGERID OTC- omeprazole and sodium bicarbonate capsule, gelatin coated
Bayer HealthCare LLC.

Zegerid OTC

Drug Facts

Active ingredients (in each capsule)

Omeprazole 20 mg

Sodium Bicarbonate 1100 mg

Purpose

Acid reducer

Allows absorption of this omeprazole product

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
- bloody or black stools

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.
- 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**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)
- any other prescription drugs. Sodium bicarbonate 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 (1-800-1222).

Directions

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, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water at least 1 hour before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- do not chew or crush the capsule
- do not open capsule and sprinkle on food

- do not use for more than 14 days unless directed by your doctor

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

Other information

- each tablet contains: **sodium 303 mg**
- read the directions, warnings and accompanying label information before use
- store at 20°-25°C (68°-77°F)
- tamper-evident: do not use if the blue band around the capsule is missing or broken. Do not use if foil inner seal imprinted with "Sealed for your protection" is missing, open or broken.
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients

FD&C blue No. 1, FD&C blue No. 2 aluminum lake, FD&C red No. 40, gelatin, polysorbate 80, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide

Questions or comments

Questions or comments?

Call **1-888-4-ZEG-OTC (1-888-493-4682)** between 9:00 AM and 5:00 PM Eastern Standard Time, Monday through Friday

42 count carton

Treats Frequent Heartburn

Zegerid OTC ®

- Omeprazole 20 mg/Acid Reducer
- Sodium Bicarbonate 1100 mg/
Allows Absorption of this Omeprazole Product

42 CAPSULES

Three 14-Day Courses of Treatment



ZEGERID OTC			
omeprazole and sodium bicarbonate capsule, gelatin coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-7276
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)		OMEPRAZOLE	20 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4MONH37)		SODIUM BICARBONATE	1100 mg
Inactive Ingredients			
Ingredient Name			Strength
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)			

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (blue band)	Score	no score
Shape	OVAL	Size	23mm
Flavor		Imprint Code	ZEG
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-7276-1	1 in 1 CARTON	10/01/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11523-7276-2	1 in 1 CARTON	10/01/2017	
2		42 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	ANDA201361	10/01/2017	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2024

Bayer HealthCare LLC.