

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

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**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-7276
<b>Route of Administration</b>	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:LYR4M0NH37)	SODIUM BICARBONATE	1100 mg

## Inactive Ingredients

Ingredient Name	Strength
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

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

### 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: 5/2018

Bayer HealthCare LLC.