

**ZEGERID OTC- omepraole, sodium bicarbonate capsule, gelatin coated  
Riley Consumer Care LLC**

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**Riley Consumer Care LLC DBA Carlin Consumer Healthcare Drug Facts**

**Active ingredients (in each capsule)**

Omeprazole 20 mg

Sodium Bicarbonate 1100 mg.... Allows absorption of this omeprazole product

**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
- a sodium-restricted diet

### **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, 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 (in 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: **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?

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

## Package/Label Principal Display Panel

CLINICALLY PROVEN TO Treat Frequent Heartburn

Zegerid OTC®

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

14 CAPSULES

24 HOUR

One 14-Day Course of Treatment

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

## HOW ZEGERID OTC WORKS FOR YOUR FREQUENT HEARTBURN

Zegerid OTC works differently from other OTC heartburn products, such as antacids and other acid reducers. Zegerid OTC stops acid production at the source - the acid pump that produces stomach acid. Zegerid OTC is to be used once a day (every 24 hours), every day for 14 days.

### TIPS FOR MANAGING HEARTBURN

- Do not lie flat or bend over soon after eating
- Do not eat late at night or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose-fitting clothing around your stomach

CLINICALLY PROVEN TO  
*Treat Frequent Heartburn*

# Zegerid<sup>®</sup>

OTC<sup>®</sup>

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1H9D5 XL C-1

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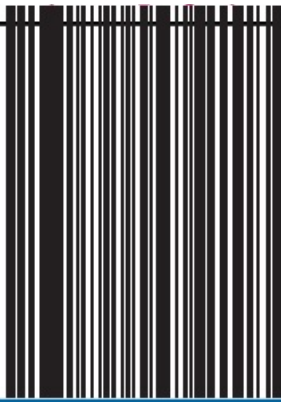
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- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, ▶



**Drug Facts (continued)**

- 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
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**Inactive ingredients**

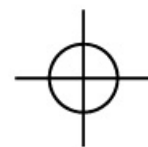
FD&C blue no. 1, FD&C blue no. 2 aluminum lake, FD&C red no. 40, gelatin, polysorbate 80, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide

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Zegerid OTC design logo is a registered trademark of Riley Consumer Care, LLC d/b/a Carlin Consumer Health  
Zegerid OTC is a registered trademark of Santarus, Inc.

Dist by: Riley Consumer Care, LLC d/b/a Carlin Consumer Health  
New York, NY 10151



**ZEGERID OTC**

omeprazole, sodium bicarbonate capsule, gelatin coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82632-699
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OMEPRAZOLE</b> (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1100 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE (BLUE BAND)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	23mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82632-699-01	1 in 1 CARTON	01/10/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:82632-699-03	1 in 1 CARTON	01/10/2024	
2		42 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA201361	01/10/2024	

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**Labeler** - Riley Consumer Care LLC (118598784)

Revised: 1/2024

Riley Consumer Care LLC