

ZEGERID OTC - omeprazole and sodium bicarbonate capsule
RILEY CONSUMER CARE, LLC

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.
- 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 (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: **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

citric acid anhydrous, croscarmellose sodium, FD&C blue #1 aluminum lake, gelatin, magnesium stearate, polysorbate 80, potassium sorbate, propylene glycol, shellac, sodium lauryl sulphate and 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

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

Dist by:

Riley Consumer Care, LLC

d/b/a Carlin

Consumer Health
New York, NY 10151

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg/1100 mg (14 Capsules Container Label)

CLINICALLY PROVEN TO
Treat Frequent Heartburn

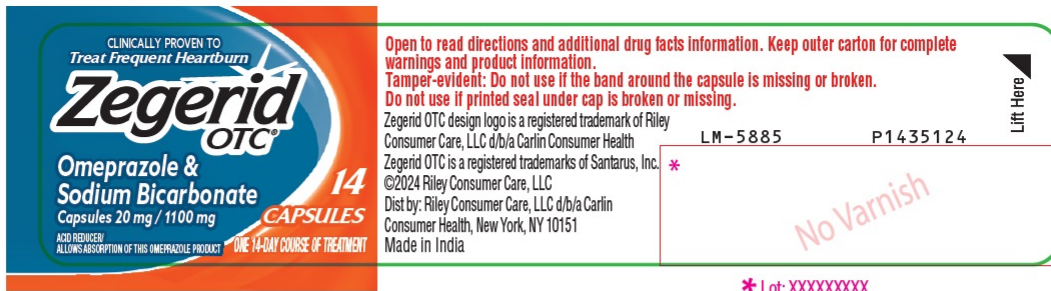
Zegerid
OTC[®]

Omeprazole &
Sodium Bicarbonate
Capsules 20 mg / 1100 mg

ACID REDUCER/
ALLOWS ABSORPTION OF THIS OMEPRAZOLE PRODUCT

14
CAPSULES

ONE 14-DAY COURSE OF TREATMENT



Top Ply (Page #1)

* Lot: XXXXXXXX
EXP: MM/YYYY
Neutral code shall be printed
online during packing

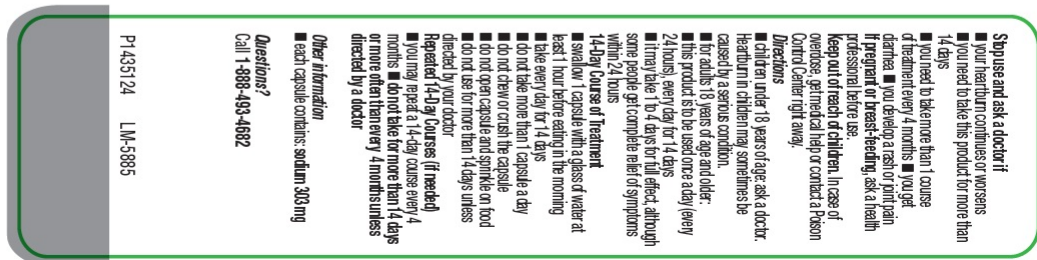


Back of Top Ply (Page #2)

Bottom Ply

Second Layer

Base (Page #3)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg/1100 mg (14 Capsules Container Carton Label)

CLINICALLY PROVEN TO
Treat Frequent Heartburn

**Zegerid
OTC®**

Omeprazole &

Sodium Bicarbonate
Capsules 20 mg / 1100 mg

ACID REDUCER/
ALLOWS ABSORPTION OF THIS OMEPRAZOLE PRODUCT

24 HOUR

14
CAPSULES

One 14-Day Course of Treatment

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



ZEGERID OTC
omeprazole and sodium bicarbonate capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82632-101
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) (BICARBONATE ION - UNII:HN1ZRA3Q20)			SODIUM BICARBONATE	1100 mg
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE (Blue band)	Score	no score	
Shape	CAPSULE	Size	24mm	
Flavor		Imprint Code	ZEG	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82632-101-01	1 in 1 CARTON	12/22/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:82632-101-03	3 in 1 CARTON	12/22/2023	
2		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	ANDA204923		12/22/2023	

Labeler - RILEY CONSUMER CARE, LLC (118598784)

Registrant - Aurohealth LLC (078728447)

