

OMEPRAZOLE AND SODIUM BICARBONATE - omeprazole and sodium bicarbonate capsule
Aurohealth 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° to 25°C (68° to 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 **1-855-274-4122**

How Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg Works For Your Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg works differently from other OTC heartburn products, such as antacids and other acid reducers. Omeprazole and Sodium Bicarbonate Capsules stops acid production at the source - the **acid pump** that produces stomach acid. Omeprazole and Sodium Bicarbonate Capsules 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

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

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

**AUROHEALTH
NDC 58602-725-05**

CLINICALLY PROVEN TO
Treats Frequent Heartburn

**Omeprazole and Sodium
Bicarbonate Capsules**

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

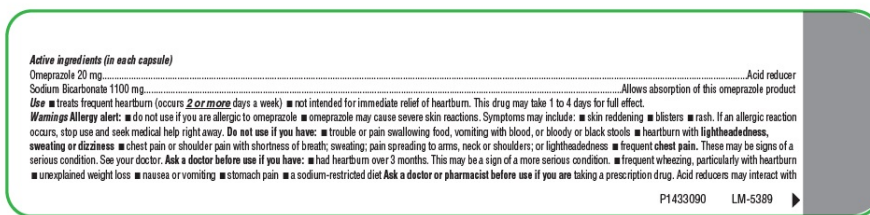
14 Capsules
One 14-Day Course of Treatment
May Take 1 to 4 days for full effect

Top Ply



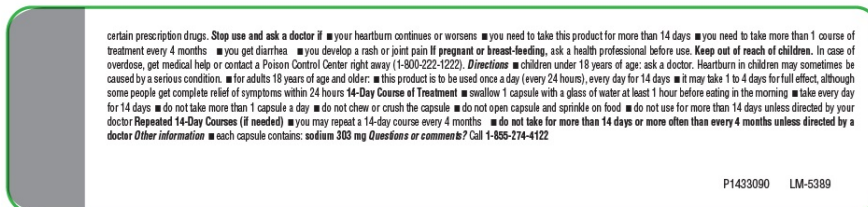
Top Ply (Page #1)

* Lot: XXXXXXXX
 EXP: MM/YYYY
 Prefix & Variables of Lot, EXP shall be printed online during packing.



Back of Top Ply (Page #2)

Bottom Ply



Base (Page #3)

Labeling Format Information:	
Font type :	Helvetica Condensed
Barline :	NA
Hairline :	NA
Drug facts :	NA
Drug facts (continued):	NA
Header :	5
Subheader :	5 pt
Leading :	0.5 pt
Body text :	5 pt
Bullets :	5 pt

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

AUROHEALTH
NDC 58602-725-05

*Compare to Zegerid OTC® Capsules
 Active Ingredients

CLINICALLY PROVEN TO
Treats Frequent Heartburn

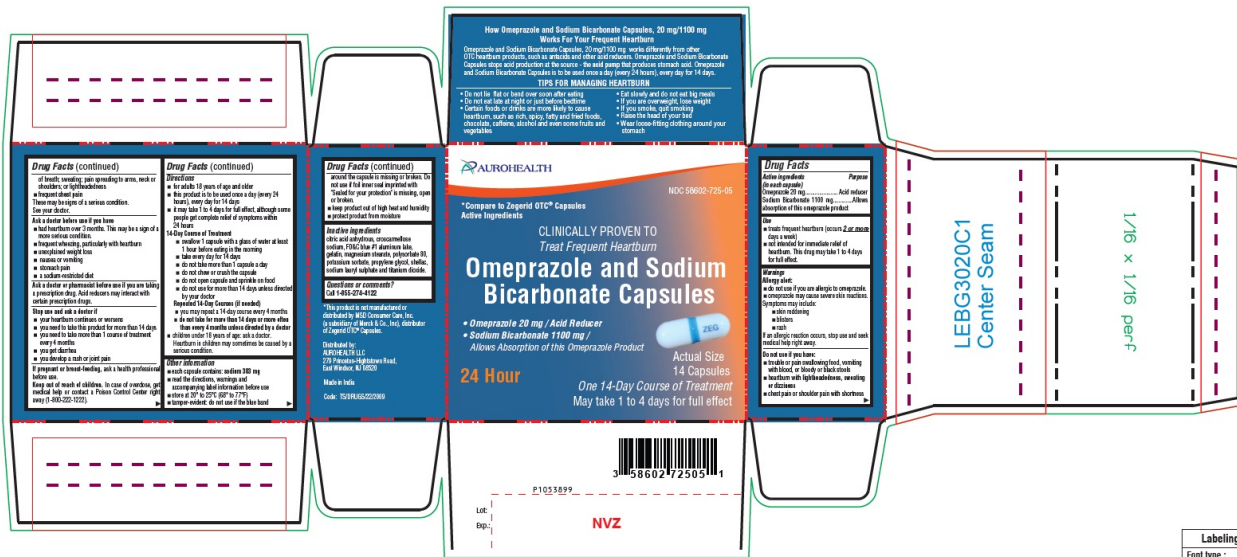
Omeprazole and Sodium Bicarbonate Capsules

- **Omeprazole 20 mg / Acid Reducer**
- **Sodium Bicarbonate 1100 mg /**
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*



Labeling Format Information:	
Font type :	Helvetica Condensed
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Headline :	0.5
Drug facts :	9 pt
Drug facts (continued) :	8 pt
Header :	7 pt
Subheader :	6 pt
Leading :	0.5 pt
Body text :	6 pt
Bullets :	5 pt

OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-725
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:58602-725-05	1 in 1 CARTON	12/22/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-725-60	3 in 1 CARTON	12/22/2023	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-725-57	2 in 1 CARTON	12/22/2023	
3		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 - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-725) , MANUFACTURE(58602-725)

Revised: 6/2024

Aurohealth LLC