OMEPRAZOLE AND SODIUM BICARBONATE - omeprazole and sodium bicarbonate capsule Aurolife Pharma, LLC

Active ingredient(s)

Omeprazole 20 mg Sodium Bicarbonate 1100 mg

Purpose

Acid reducer Allows absorption of this omeprazole product

Use(s)

- treats frequent heartburn (occurs *2 or more* days a week)
- not intended for immediate relief of hearburn. 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:

- touble 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 diziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulder; 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 medicine)
- prescription antiretrovirals (medicines for HIV infection)
- Methotrexate (arthiritis 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

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 contract a Poison Control Center right away.

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 one 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 ofen than every 4 months unless directed by a doctor
- children under 18 years of age; ask a doctor. Heartburn in children may sometines be caused by a serious condition.

Other information

- each capsule contains: sodium 303 mg
- read the direction, 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 is missing, open or broken.
- keep product out of high heat and humidity
- prtect product from moisture

Inactive Ingredients

citric acid, croscarmellose sodium, FD&C Blue # 1, FD&C Red # 3, gelatin, magnesium stearate NF, pharmaceutical ink, polysorbate 80, potassium hydroxide NF, potassium sorbate, propylene glycol, Shellac, sodium lauryl sulphate, titanium dioxide,

Questions or Comments?

Call toll-free 1-866-850-2876

How Omeprazole and Sodium Bicarbonate Capsules Work For Your Frequent Heartburn

Omeprazole and sodium bcarbonate capsules work differently form other OTC heartburn products, such as antacids and other acid reducers. Omeprazole and sodium bicarbonate capsules stop acid production at the source-the **acid pump** that produces stomach acid. Omeprazole and sodium bicarbonate capsules are to be used once a day (every 24 hours), every day for 14 days.

What to Expect When Using Omeprazole and Sodium Bicarbonate Capsules

Omeprazole and sodium bicarbonate capsules is a different type of medicine from antacids and other acid reducers. Omeprazole and sodium bicarbonate capsules may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

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 likeling 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.

How are Omeprazole and Sodium Bicarbonate Capsules Sold

Omeprazole and sodium bicarbonate capsules are available in 14, 28 and 42 count sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use of more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

PRINCIPAL DISPLAY PANEL - 14 Capsule Carton

* Compare to Zegerid OTC[®] Capsules Active Ingredients

NDC 13107-117-14

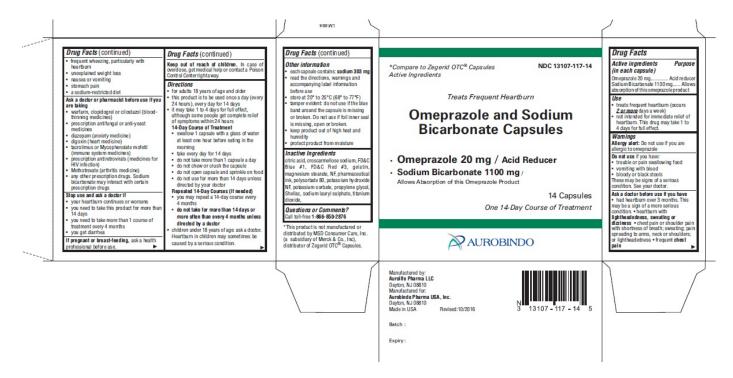
Treats Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules

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

14 Capsules One 14-Day Course of Treatment

Aurobindo



PRINCIPAL DISPLAY PANEL - 28 Capsule Carton

* Compare to Zegerid OTC[®] Capsules Active Ingredients

NDC 13107-117-28

Treats Frequent Heartburn

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

28 Capsules Two 14-Day Course of Treatment

Aurobindo



PRINCIPAL DISPLAY PANEL - 42 Capsule Carton

* Compare to Zegerid OTC[®] Capsules Active Ingredients

NDC 13107-117-42

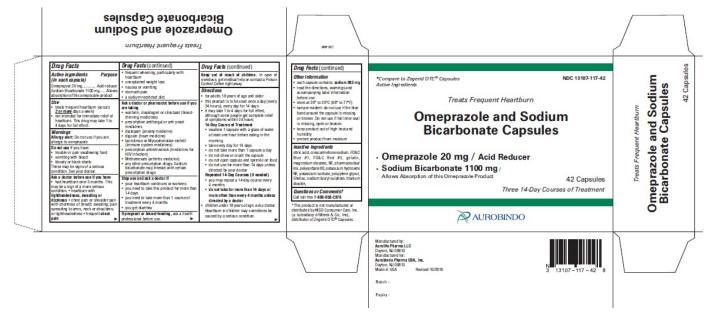
Treats Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules

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

42 Capsules Three 14-Day Course of Treatment

Aurobindo



Product Information						
Product Type	HUMAN OTC DRUG	tem Code (Source)	NDC:13107-117		
Route of Administration	ORAL					
Active Ingredient/Active Mo	iety					
Ir	ngredient Name		Basis of S	Strength	Strengt	
OMEPRAZOLE (UNII: KG60484QX9)	(OMEPRAZOLE - UNII:KG60484Q2	K9)	OMEPRAZOL	Æ	20 mg	
SODIUM BICARBONATE (UNII: 8 MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20) SODIUM BICA					1100 mg	
	Ingredient Name			Stre	ngth	
	Ingredient Name			Stre	ngth	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)						
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)						
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)						
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)						
GELATIN (UNII: 2G86QN327L)						
MAGNESIUM STEARATE (UNII: 70097M6I30)						
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)						
POTASSIUM HYDROXIDE (UNII: WZH3C48 M4T)						
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
	SHELLAC (UNII: MB5IUD6JUA)					
SHELLAC (UNII: MB5IUD6JUA)						

Product Characteristics				
Color BLUE (Light Blue Opaque Cap), WHITE (White Opaque Body) Score		Score	no score	
Shape	CAPSULE (Capsule)	Size	24mm	
Flavor		Imprint Code	U;96	
Contains				

Packaging

I uckuging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:13107-117-14	1 in 1 CARTON	09/30/2014			
1		14 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:13107-117-28	2 in 1 CARTON 09/30/2014				
2		14 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:13107-117-42	3 in 1 CARTON 09/30/2014				
3		14 in 1 BOTTLE; Type 0: Not a Combination Product				
Marketing Information						
N	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
A	NDA	ANDA204923	09/30/2014			

Labeler - Aurolife Pharma, LLC (829084461)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aurolife Pharma, LLC		829084461	MANUFACTURE(13107-117)	

Establishment

Name	Address	ID/FEI	Business Operations
Aurolife Pharma LLC		078296263	RELABEL(13107-117), REPACK(13107-117), LABEL(13107-117), PACK(13107-117)

Revised: 9/2019

Aurolife Pharma, LLC