

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 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 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 (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

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.

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 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 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
- protect 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 bicarbonate capsules work differently from 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 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.

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 for 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 Omeprazole Product

14 Capsules

One 14-Day Course of Treatment

Aurobindo

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain • a sodium-restricted diet <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> • warfarin, clopidogrel or cilostazol (blood-thinning medicines) • prescription antifungal or anti-yeast medicines • diazepam (anxiety medicine) • digoxin (heart medicine) • sacralimus 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. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • 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 <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> • 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. 	<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> • each capsule contains: sodium 308 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 is missing, open or broken. • keep product out of high heat and humidity • protect product from moisture <p>Inactive Ingredients</p> <p>citric acid, croscarmellose sodium, FD&C Blue #1, FD&C Red #3, gelatin, magnesium stearate, NF, pharmaceutical ink, polyorbate 80, potassium hydroxide NF, potassium sorbate, propylene glycol, Shellac, sodium lauryl sulphate, titanium dioxide.</p> <p>Questions or Comments? Call toll-free 1-866-850-2876</p> <p><small>* This product is not manufactured or distributed by MSD Consumer Care, Inc. (a subsidiary of Merck & Co., Inc.), distributor of Zegerid OTC® Capsules.</small></p>	<p>*Compare to Zegerid OTC® Capsules Active Ingredients</p> <p style="text-align: right;">NDC 13107-117-14</p> <p style="text-align: center;">Treats Frequent Heartburn</p> <h2 style="text-align: center;">Omeprazole and Sodium Bicarbonate Capsules</h2> <ul style="list-style-type: none"> • Omeprazole 20 mg / Acid Reducer • Sodium Bicarbonate 1100 mg / Allows Absorption of this Omeprazole Product <p style="text-align: right;">14 Capsules One 14-Day Course of Treatment</p> <p style="text-align: center;"> AUROBINDO</p>	<p>Drug Facts</p> <p>Active ingredients (in each capsule)</p> <p>Omeprazole 20 mg..... Acid reducer Sodium Bicarbonate 1100 mg..... Allows absorption of this omeprazole product</p> <p>Use</p> <ul style="list-style-type: none"> • 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. <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> • trouble or pain swallowing food • vomiting with blood • bloody or black stools <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> • 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
<p>Manufactured by: Aurobindo Pharma LLC Dayton, NJ 08810 Manufactured for: Aurobindo Pharma USA, Inc. Dayton, NJ 08810 Made in USA Revised:10/2016</p> <p>Batch : Expiry:</p>			 <p>N 3 13107 - 117 - 14 5</p>	

PRINCIPAL DISPLAY PANEL - 28 Capsule Carton

*** Compare to Zegerid OTC® Capsules**
Active Ingredients

NDC 13107-117-28

Treats Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules

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

28 Capsules
Two 14-Day Course of Treatment

Aurobindo

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain • a sodium-restricted diet <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> • 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 <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • 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 <p>Repeated 14-Day Courses (If needed)</p> <ul style="list-style-type: none"> • 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 <p>• children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>	<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> • 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 is missing, open or broken. • keep product out of high heat and humidity • protect product from moisture <p>Inactive Ingredients</p> <p>citric acid, croscarmellose sodium, FD&C Blue #1, FD&C Red #3, gelatin, magnesium stearate, NF, pharmaceutical ink, polysorbate 80, potassium hydroxide, NF, potassium carbonate, propylene glycol, Shellac, sodium lauryl sulphate, titanium dioxide.</p> <p>Questions or Comments? Call toll-free 1-866-859-2876</p> <p><small>*This product is not manufactured or distributed by MSD Consumer Care, Inc. (a subsidiary of Merck & Co., Inc), distributor of Zegerid OTC® Capsules.</small></p>	<p><i>*Compare to Zegerid OTC® Capsules</i> NDC 13107-117-28</p> <p><i>Active Ingredients</i></p> <p><i>Treats Frequent Heartburn</i></p> <p>Omeprazole and Sodium Bicarbonate Capsules</p> <ul style="list-style-type: none"> • Omeprazole 20 mg / Acid Reducer • Sodium Bicarbonate 1100 mg / Allows Absorption of this Omeprazole Product <p>28 Capsules Two 14-Day Courses of Treatment</p> <p>AUROBINDO</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients (in each capsule)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Omeprazole 20 mg</td> <td>Acid reducer</td> </tr> <tr> <td>Sodium Bicarbonate 1100 mg</td> <td>Allows absorption of this omeprazole product</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> • 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. <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole.</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> • trouble or pain swallowing food • vomiting with blood • bloody or black stools <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with lightheadedness, swelling or dizziness • chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness • frequent chest pain 	Active ingredients (in each capsule)	Purpose	Omeprazole 20 mg	Acid reducer	Sodium Bicarbonate 1100 mg	Allows absorption of this omeprazole product
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<p>Manufactured by: Aurobindo Pharma LLC Dayton, NJ 08810 Manufactured for: Aurobindo Pharma USA, Inc. Dayton, NJ 08810 Made in USA Revised:10/2016</p>			 <p>3 13107 - 117 - 28 2</p>	<p>Batch :</p>						

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 Omeprazole Product

42 Capsules
Three 14-Day Course of Treatment

Aurobindo

Omeprazole and Sodium Bicarbonate Capsules
Treats Frequent Heartburn

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p>Active ingredients (in each capsule)</p> <p>Omeprazole 20 mg Acid reducer Sodium Bicarbonate 1100 mg Alleviates absorption of this combination product.</p> <p>Use</p> <ul style="list-style-type: none"> • 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. <p>Warnings</p> <p>Always alert: Do not use if you are allergic to omeprazole.</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> • trouble or pain swallowing food • vomiting with blood • bloody or black stools <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with light to dark stools, 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 	<p>Warnings (continued)</p> <ul style="list-style-type: none"> • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain • a sodium-restricted diet. <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> • warfarin, clozapine or citalopram (blood-thinning medicines) • prescription anti-fungal or anti-yeast medicines • cefepim (antibiotic medicine) • digoxin (heart medicine) • tacrolimus or Mycophenolate mofetil (immune system medicines) • prescription anti-retroviral (medicines for HIV infection) • Methanesulfonamide (antibiotic medicine) • any other prescription drugs. Sodium bicarbonate may interact with certain prescription drugs. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • your heartburn continues or worsens • you need to take more than 1 course of treatment every 4 months • you get diarrhea <p>If pregnant or breast-feeding, ask a health-care provider before use.</p>	<p>Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 14 hours. <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • 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 <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> • 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.

Omeprazole and Sodium Bicarbonate Capsules
Treats Frequent Heartburn

NDC 13107-117-42

Omeprazole and Sodium Bicarbonate Capsules

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

42 Capsules
Three 14-Day Courses of Treatment

 AUROBINDO

Manufactured by:
Aurobindo Pharma LLC
Chennai, NJ 08010
Manufactured for:
Aurobindo Pharma USA, Inc.
Chennai, NJ 08010
Made in USA Revised: 10/2016


 3 13107-117-42 8

Omeprazole and Sodium Bicarbonate Capsules
Treats Frequent Heartburn

42 Capsules

OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13107-117
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELOSE 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: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: MB5IUD6JUA)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	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