

OMEPRAZOLE AND SODIUM BICARBONATE- omeprazole and sodium bicarbonate capsule
Zydus Pharmaceuticals USA Inc.

Omeprazole and Sodium Bicarbonate Capsules

Drug Facts

Active ingredients (in each capsule)

Omeprazole, USP20 mg

Sodium Bicarbonate, USP1100 mg

Purpose

Omeprazole, USPAcid reducer

Sodium Bicarbonate, USPAllows 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

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 shoulders; 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

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 breastfeeding, 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 at 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 301.34 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 ingredient

croscarmellose sodium, FD&C blue # 1, gelatin, magnesium stearate, polysorbate 80, sodium lauryl sulfate and titanium dioxide. The capsule shell is printed with black pharmaceutical ink which contains following ingredients: black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac and strong ammonia solution.

Questions or comments?

Serious side effects associated with use of this drug product may be reported to this number: 1-877-993-8779 or visit www.zydususa.com

Hours of operation:

9:00 am to 5:00 pm

EST M-F.

You may report side effects to FDA at 1-800-FDA-1088.

How Omeprazole and Sodium Bicarbonate Capsule Works For Your Frequent Heartburn

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

What to Expect When Using Omeprazole and Sodium Bicarbonate Capsule

Omeprazole and sodium bicarbonate capsule is a different type of medicine from antacids and other acid reducers. Omeprazole and sodium bicarbonate capsule 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, 20 mg/1100 mg are white to off-white fine powder filled in hard gelatin capsule shells of size '00' having an opaque white cap and an opaque white body printed with '503' on body in black ink and a blue tamper evident band and are available as follows:

NDC 68382-503-67 in one HDPE bottle of 14 capsules

NDC 68382-503-17 in two HDPE bottles of 28 capsules (one bottle contains 14 capsules)

NDC 68382-503-04 in three HDPE bottles of 42 capsules (one bottle contains 14 capsules)

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.

Manufactured by:

Cadila Healthcare Ltd.

Ahmedabad, India

Distributed by:

Zydus Pharmaceuticals (USA) Inc.

Pennington, NJ 08534

Rev.: 02/19

Carton and container labels

NDC 68382-503-67

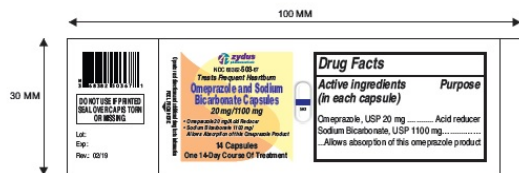
Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg

14 Capsules

Zydus

ATTACH LEGEND ON ALL
DIGITAL MECHANICALS

STANDARD FORMAT
Helvetica Name
Variable horizontal scale adheres to 30 characters per inch
Drug Facts - 10 pt Helvetica Name; Bold Italic
Drug Facts (continued)
Drug Facts - 8 pt Helvetica Name; Bold Italic
(continued) - 8 pt Helvetica Name
Headings - 8 pt Helvetica Name; Bold Italic
Sub-Headings - 6 pt Helvetica Name; Bold
Text - 6 pt Helvetica Name; Minimum leading 6.5
Footnote/Notes - 6 pt Helvetica Name; No compression
Barcode - 3 pt Helvetica
Bottom - 3 pt Helvetica
Bottom - 3 pt Helvetica



<p>Drug Facts (continued)</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>Drug Facts (continued)</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>Asks 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. 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> heartburn with light-headedness, swelling or dizziness chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or light-headedness frequent chest pain frequent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> a sodium-restricted diet. <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> you need to take more than 1 course of treatment every 6 months you get diarrhea you develop a rash or joint pain <p>If pregnant or breastfeeding, ask a health professional before use.</p>
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<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away at 1-800-222-1222.</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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none"> each capsule contains: sodium 301.34 mg read the directions, warnings and accompanying label information before use store at 20° to 25° C (68° to 77° F) 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> tamper-evident: do not use if the blue band around the capsule is missing or broken. Do not use full 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
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<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>croscarmellose sodium, FD&C blue #1, gelatin, magnesium stearate, polypropylene 30, sodium lauryl sulfate and titanium dioxide. The capsule shell is printed with black pharmaceutical ink which contains following ingredients:</p>	<p>Drug Facts (continued)</p> <p>black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac and strong ammonia solution.</p>	<p>Drug Facts (continued)</p> <p>Questions or comments?</p> <p>Serious side effects associated with use of this drug product may be reported to this number:</p> <p>1-877-993-8779 or visit www.zydususa.com</p> <p>Hours of operation:</p> <p>9:00am to 5:00pm EST M-F.</p>	<p>How Omeprazole and Sodium Bicarbonate Capsule Works For Your Frequent Heartburn</p> <p>Omeprazole and sodium bicarbonate capsule works differently from other OTC heartburn products, such as antacids and other acid reducers. Omeprazole and sodium bicarbonate capsule stops acid production at the source - the acid pump that produces stomach acid.</p>	<p>Omeprazole and sodium bicarbonate capsule is to be used once a day (every 24 hours), every day for 14 days.</p> <p>What to Expect When Using Omeprazole and Sodium Bicarbonate Capsule</p> <p>Omeprazole and sodium bicarbonate capsule is a different type of medicine from antacids and other acid reducers. Omeprazole and sodium</p>	<p>bicarbonate capsule 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.</p> <p>Tips for Managing Heartburn</p> <ul style="list-style-type: none"> 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
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<p>heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some fruits and vegetables.</p> <ul style="list-style-type: none"> Eat slowly and do not eat big meals. If you are overweight, lose weight. 	<ul style="list-style-type: none"> Try smoking, gum chewing. Raise the head of your bed. Wear loose-fitting clothing around your stomach. 	<p>How are Omeprazole and Sodium Bicarbonate Capsules Sold</p> <p>Omeprazole and Sodium Bicarbonate Capsules are available as follows:</p> <p>NDC 68382-503-67 in one HDPE bottle of 14 capsules</p> <p>NDC 68382-503-17 in two HDPE bottles of 28 capsules (one bottle contains 14 capsules)</p>	<p>NDC 68382-503-04 in three HDPE bottles of 42 capsules (one bottle contains 14 capsules)</p> <p>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.</p>	<p>Manufactured by:</p> <p>Cell-I-H-Healthcare Ltd.</p> <p>Ahmedabad, India</p> <p>Distributed by:</p> <p>Zydus Pharmaceuticals (USA) Inc.</p> <p>Parsippany, NJ 08054</p>	
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MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	WHITE (OPAQUE WHITE) , WHITE (OPAQUE WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	24mm
Flavor		Imprint Code	503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-503-17	2 in 1 CARTON	07/19/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68382-503-67	1 in 1 CARTON	07/19/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68382-503-04	3 in 1 CARTON	07/19/2018	
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	ANDA203345	07/19/2018	

Labeler - Zydus Pharmaceuticals USA Inc. (156861945)

Registrant - Zydus Worldwide DMCC (557951127)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(68382-503) , MANUFACTURE(68382-503)

Revised: 6/2023

Zydus Pharmaceuticals USA Inc.