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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.

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.

NC

NO COATING

0.750

1.750

1.583

NO COATING

NC

Actavis NDC 45963-441-40

Compare to the active ingredients in Zegerid OTC.*

Treats Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules

20 mg/1100 mg

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

One-14-Day Course of Treatment

14 capsules

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ACTUAL SIZE

NC

LOT: _____

EXP: **NO COAT**

N 45963 44140 9

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NO COATING

Drug Facts (continued)

Other information

- each capsule contains sodium 300 mg
- read the directions, warnings and accompanying label information before use.
- store at room temperature between 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 "Shield for your protection" is missing, open or broken.
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients

croscarmellose sodium, FD&C blue #1, gelatin, polyorbate 90, sodium lauryl sulfate, sodium stearyl fumarate and titanium dioxide. Printing ink contains black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, polyethylene glycol, purified water, shellac and strong ammonia solution.

Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

This product is not affiliated with, manufactured by or produced by the makers or owners of Zegerid OTC.

Manufactured for: Actavis Pharma, Inc. Parsippany, NJ 07054 USA

Made in India DP19537
04410216 Rev. 02/16

Drug Facts

Active ingredients (in each capsule)

Omeprazole, USP 20 mg
Sodium Bicarbonate, USP 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

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:

- warfarin, clopidogrel or clostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diclofenac (arthritis medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)

Drug Facts (continued)

Purpose

- 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 (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.

FONTS: Myriad Pro – roman, bold, bold italic, black, black italic; Helvetica condensed medium, condensed bold, condensed bold oblique.

Drug Facts: 10 pt
Headers: 8 pt
Body text: 6 pt
Drug Facts (continued): 8 pt
Leading: 6.5 pt
Bullets: 6 pt
Frames: 1.5 pt
Bars: 1 pt
Rules: 0.75 pt



(b) (4)

LEAFLET INSIDE PRINTING

LEAFLET OUTSIDE PRINTING

Drug Facts (continued)

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

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Open to read directions and additional drug facts information

NDC 45963-441-40

Omeprazole and Sodium Bicarbonate

Capsules 20 mg/1100 mg

• Omeprazole 20 mg Acid Reducer
 • Sodium Bicarbonate 1100 mg/Allow Absorption of this Omeprazole Product
One-14-Day Course of Treatment
 14 capsules

Drug Facts

Active ingredients (in each capsule)	Purpose
Omeprazole, USP 20 mg	Acid reducer
Sodium Bicarbonate, USP 1100 mg	Acid reducer
...Allows absorption of this omeprazole product	

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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 (two 14-day courses) and 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

Drug Facts (continued)

- 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

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Drug Facts (continued)

- 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

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.

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Drug Facts (continued)

any other prescription drugs. Sodium bicarbonate may interact with certain prescription drugs.

Stop use and ask a doctor if:

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- 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.

Drug Facts (continued)

Inactive ingredients

croscarmellose sodium, FD&C blue #1, gelatin, polyacrylate 80, sodium lauryl sulfate, sodium stearyl fumarate and titanium dioxide. Printing ink contains black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac and strong ammonia solution.

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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 are 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.

Drug Facts (continued)

- ask a doctor or pharmacist before use if you are taking
- warfarin, clopidogrel or cimetidine (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretroviral (medicines for HIV infection)
- methotrexate (arthritis medicine)

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Drug Facts (continued)

- store at room temperature between 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

Drug Facts (continued)

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

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Drug Facts (continued)

- swallow 1 capsule with a glass of water at least 1 hour before eating in the morning
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- 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

Drug Facts (continued)

- 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.

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Treats Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules

20 mg/1100 mg

• Omeprazole 20 mg Acid Reducer
• Sodium Bicarbonate 1100 mg/ Allow Absorption of this Omeprazole Product

NDC 45963-441-40
One-14-Day Course of Treatment
Manufactured for:
Actavis Pharma, Inc.
Parsippany, NJ 07054-USA
Made in India
Rev. 02/16
DP19540
04410216

14 capsules

BASE LABEL With Liner



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