

OMEPRAZOLE AND SODIUM BICARBONATE- omeprazole, sodium bicarbonate capsule, gelatin coated
CVS Pharmacy

CVS Pharmacy, Inc. Omeprazole & Sodium Bicarbonate 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 20-25°C (68-77°F)
- tamper-evident: Do not use if the band around the capsule is missing or broken. Do not use if printed seal under cap is broken or missing.
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients

FD&C blue no. 1, FD&C blue no. 2 aluminum lake, FD&C red no. 40, gelatin, polysorbate 80, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

CVS Health®

Compare to the active ingredients in Zegerid OTC®

Clinically Proven To Treat Frequent Heartburn

Omeprazole & Sodium Bicarbonate

Capsules, 20 mg/1100 mg

24 HOUR

- Acid Reducer
- Allows Absorption of this Omeprazole Product

Actual Bottle Size on Side Panel

Package Contains Three Bottles

42 CAPSULES

Three 14-day courses of treatment

May take 1 to 4 days for full effect

Actual Size

How Omeprazole and Sodium Bicarbonate Capsules Works For Your Frequent Heartburn

Omeprazole and Sodium Bicarbonate Capsules 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



Compare to the active ingredients in Zegerid OTC®*

NDC 59779-732-03

Clinically Proven To Treat Frequent Heartburn

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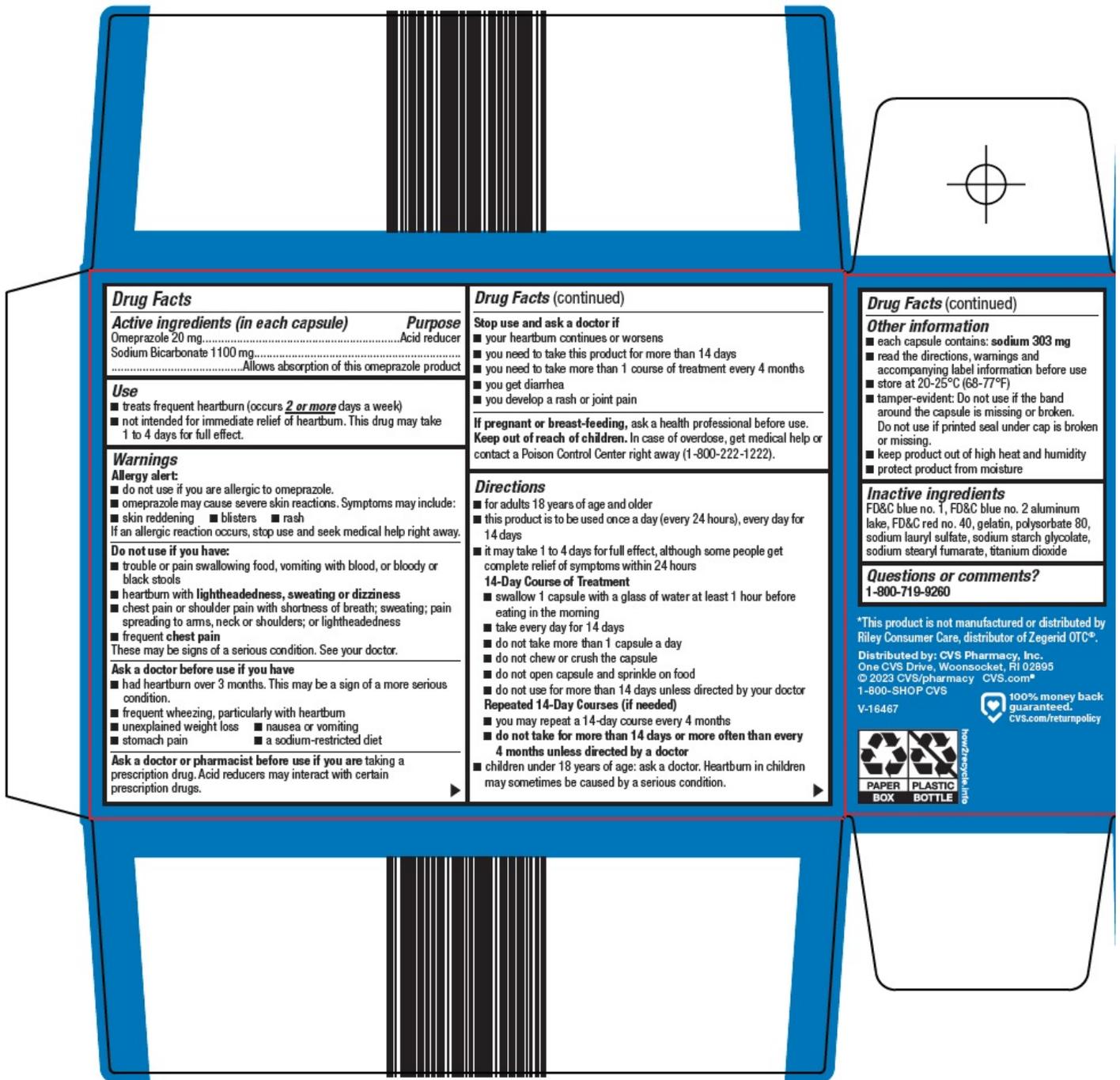


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#354621





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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

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V-16467

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OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole, sodium bicarbonate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-732
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	1100 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (blue band)	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	732
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-732-01	1 in 1 CARTON	07/15/2016	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59779-732-03	3 in 1 CARTON	07/15/2016	
2		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	ANDA201361	07/15/2016	

Labeler - CVS Pharmacy (062312574)