

OMEPRAZOLE AND SODIUM BICARBONATE- omeprazole, sodium bicarbonate capsule, gelatin coated
H E B

HEB OMEPRAZOLE AND 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

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 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

Compare to Zegerid OTC[®] active ingredients

Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg

Omeprazole, 20 mg/Acid Reducer - Sodium Bicarbonate, 1100 mg/

Allows Absorption of this Omeprazole Product

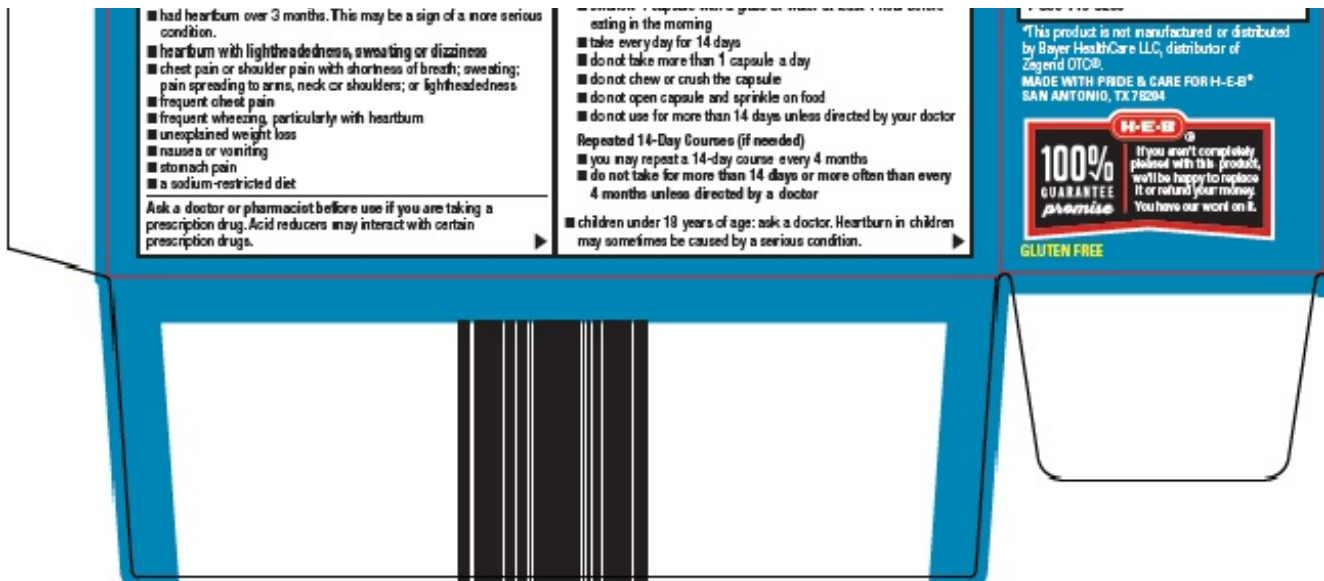
Acid Reducer

Treats Frequent Heartburn

42 CAPSULES

actual size

Three 14-day courses of treatment



OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole, sodium bicarbonate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-732
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) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1100 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UJ)	
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:37808-732-01	1 in 1 CARTON	08/25/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:37808-732-03	3 in 1 CARTON	08/25/2017	
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	08/25/2017	

Labeler - HEB (007924756)

Revised: 11/2020

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