

SODIUM BICARBONATE- sodium bicarbonate tablet
Aphena Pharma Solutions - Tennessee, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SODIUM BICARBONATE 10 gr (650 mg)

Drug Facts

Active Ingredient (in each tablet)

Sodium bicarbonate 10 gr (650 mg)

PURPOSE

Antacid

Indications:

Relieves:

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms

Warnings

Ask a doctor or pharmacist

- if you are on a sodium-restricted diet.
- if you are taking a prescription drug. Antacids may interact with certain prescription drugs.
- if symptoms last more than 2 weeks

As with any drug, if you are pregnant or nursing a baby, seek advise of a health professional before using this product.

Directions:

- Adults 60years of age and over - 1-2 tablets every 4 hours. Not more than 12 tablets in 24 hours
- Adults under 60 years- 1-4 tablets every4 hours. Not more than 24 tablets in 24 hours
- Dissolve tabelt completely in water before drinking.
- DO NOT EXCEED RECOMMENDED DOSE. Not recommended for children.

Other Information:

- each tablet contains: sodium 178 mg
- store at room temperature 15 ° - 30 °C (59 ° - 86 °F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

In case of accidental overdose, seek professional assistance or contact a poison control center

immediately.

INACTIVE INGREDIENT

croscarmellose sodium, microcrystalline cellulose, stearic acid

Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	650 mg
60	43353-162-53
90	43353-162-60
120	43353-162-70
180	43353-162-80
200	43353-162-85
360	43353-162-94

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20171213JH

PRINCIPAL DISPLAY PANEL - 650 mg

NDC 43353-162 - Sodium Bicarbonate 650 mg - Rx Only



SODIUM BICARBONATE

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43353-162(NDC:54738-020)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (White)	Score	no score
Shape	ROUND (round)	Size	11mm
Flavor		Imprint Code	AP;119
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43353-162-53	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2016	

2	NDC:43353-162-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2016	
3	NDC:43353-162-70	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2016	
4	NDC:43353-162-80	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2016	
5	NDC:43353-162-85	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/02/2016	
6	NDC:43353-162-94	360 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	05/01/2015	

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(43353-162)

Revised: 12/2017

Aphenia Pharma Solutions - Tennessee, LLC