SODIUM BICARBONATE ANTACID- 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.

4624 - Rugby

Drug Facts

Active ingredient (in each tablet)

Sodium bicarbonate 10 gr (650 mg)

Purpose

Antacid

Uses

relieves:

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

Warnings

Do not take more than 24 tablets for adults up to 60 years of age (or 12 tablets for adults 60 years of age and older) in a 24-hour period nor use the maximum dosage for more than 2 weeks, except under the advice and supervision of a physician.

Ask a doctor before use if you have a sodium restricted diet.

Ask a doctor or pharmacist before use if you are taking a prescription drug.

Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions

do not use the maximum dosage for more than 2 weeks

- tablets may be swallowed whole or dissolved in water prior to use
- adults 60 years of age and over: 1-2 tablets every 4 hours, not more than 12 tablets in 24 hours
- adults under 60 years of age: 1-4 tablets every 4 hours, not more than 24 tablets in 24 hours

Other information

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

Inactive ingredients

croscarmellose sodium, microcrystalline cellulose, silica, stearic acid and talc

Questions or comments?

1-800-645-2158

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

Distributed by:

Rugby Laboratories

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Rev. 12/16 R-29

Repackaging Information

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

Count	650 mg	
60	71610-669-53	
90	71610-669-60	
180	71610-669-80	

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:

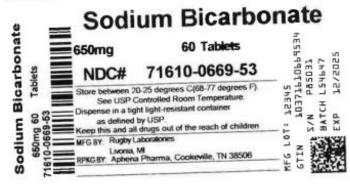


Cookeville, TN 38506

20221018JK

PRINCIPAL DISPLAY PANEL - 650 mg

NDC 71610-669 - Sodium Bicarbonate 650 mg Tablets



SODIUM BICARBONATE ANTACID

sodium bicarbonate tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-669(NDC:0536-1047)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
(0) (0) (0) (0) (0) (0) (0) (0) (0) (0)	SODIUM BICARBONATE	650 mg	

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	CPC77
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71610-669- 53	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2022		
2	NDC:71610-669- 60	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2022		
3	NDC:71610-669- 80	180 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/25/2015	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-669)	

Revised: 10/2022 Aphena Pharma Solutions - Tennessee, LLC