

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

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 drug products listed below. This drug product has been received by Aphenia Pharma Solutions - Tennessee, LLC 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:

10gr (650mg)

NDC 71610-669-53, Bottles of 60 Tablets

NDC 71610-669-60, Bottles of 90 Tablets

NDC 71610-669-80, Bottles of 180 Tablets

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

20260323BSC

PRINCIPAL DISPLAY PANEL - 650 mg

NDC 71610-669 - Sodium Bicarbonate 10gr (650 mg) Tablets

Sodium Bicarbonate 10gr

(650mg) 60 Tablets


NDC# 71610-0669-53

Store between 20-25 degrees C (68-77 degrees 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

MFG BY: Rugby Laboratories, Inc
Indianapolis, IN
RPKG BY: Aphena Pharma, Cookeville, TN 38506

Sodium Bicarbonate 10gr (650mg) 60 Tablets
71610-0669-53

MFG LOT: GTIN: 10371610669534
S/N: P050552312
BATCH: 1
EXP:



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
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	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			

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 Drug	M001	03/25/2015	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	repack(71610-669)

Revised: 3/2026

Aphenia Pharma Solutions - Tennessee, LLC