

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 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 | 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
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
Livonia, MI
RPKG BY: Aphena Pharma, Cookeville, TN 38506

MFG LOT: 12345
GTIN 10371610669534
S/N P85031
BATCH L54647
EXP 12/2025

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:L9R4M0NH37) | SODIUM BICARBONATE | 650 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELOSE 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 final | part331 | 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: 10/2022

Aphenia Pharma Solutions - Tennessee, LLC