

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 Tablets

SODIUM BICARBONATE - sodium bicarbonate tablet
Marlex Pharmaceuticals, Inc.

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Sodium Bicarbonate

Active ingredient (in each tablet)

Sodium bicarbonate 10 gr (650 mg)

Sodium bicarbonate 5gr (325 mg)

Purpose

Antacid

Uses

Relieves

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

Warnings

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.

Directions

- do not use the maximum dosage for more than 2 weeks
- dissolve tablets completely in water prior to use

325mg,

- **adults 60 years of age and over:** 2-8 tablets every 4 hours, not more than 24 tablets in 24 hours
- **adults under 60 years of age:** 2-8 tablets every 4 hours, not more than 48 tablets in 24 hours

650mg,

- **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 89mg (325mg)
- **store at room temperature 15°-30°C (59°-86°F) in well-closed containers as defined in the USP**

sodium 178 mg (650mg)

Inactive ingredients

Pregelatinized starch, NF and mineral oil, USP

Questions or comments?

Call toll free 1-888-266-8818

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

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	71610-445-53
90	71610-445-60
180	71610-445-80

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

20200723JH

PRINCIPAL DISPLAY PANEL - 650 mg

NDC 71610-445 - Sodium Bicarbonate 650 mg Tablets



SODIUM BICARBONATE

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-445(NDC:10135-685)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:L4R4M0NH37)	SODIUM BICARBONATE	650 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	G57

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-445-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
2	NDC:71610-445-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
3	NDC:71610-445-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/01/2020	

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

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-445)

Revised: 7/2020

Aphenia Pharma Solutions - Tennessee, LLC