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 Tablets, USP
Antacid

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

Drug Facts
Active ingredients (in each tablet)
Sodium Bicarbonate 10 gr (650mg)

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 (7.74 mEq) • store at room temperature 15°-30°C (59°-86°F) in a well closed container as defined in the USP.

Inactive Ingredients: Croscarmellose sodium NF, microcrystalline cellulose NF, silica NF, stearic acid NF and talc USP.

Questions? 1-866-562-4597

11790-11-16 REV 11/16

Manufactured for:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401

Manufactured by:
Contract Pharmacal Corp.
Hauppauge, NY 11788

Lot No.:

Exp. Date:

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	10 gr
60	71610-438-53
90	71610-438-60
120	71610-438-70
180	71610-438-80
360	71610-438-94

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.

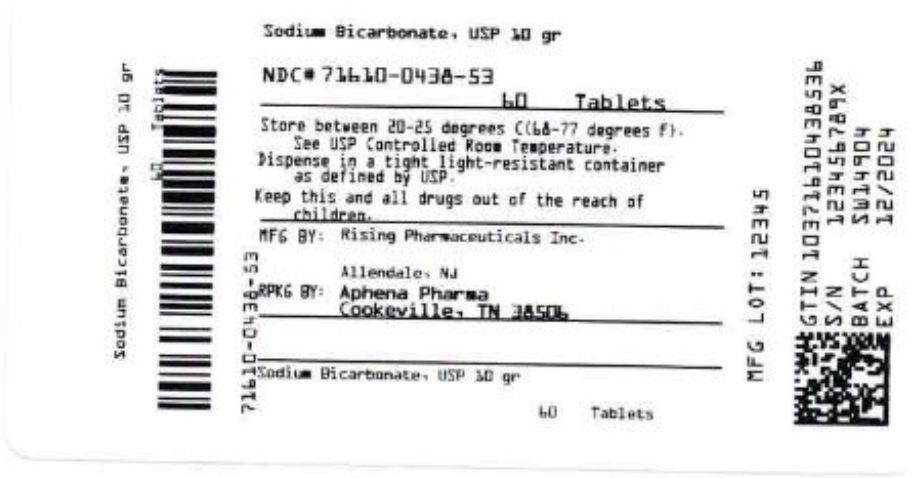
Repackaged by:

Cookeville, TN 38506

20200706JH

PRINCIPAL DISPLAY PANEL - 10 gr

NDC 71610-438 - Sodium Bicarbonate 10 gr Tablets



SODIUM BICARBONATE

sodium bicarbonate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71610-438(NDC:64980-294)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	650 mg

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

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	294;R
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71610-438-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
2	NDC:71610-438-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
3	NDC:71610-438-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
4	NDC:71610-438-94	360 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	02/01/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations

Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-438)