SODIUM BICARBONATE - sodium bicarbonate tablet, orally disintegrating
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

Drug Facts

Active ingredients (in each tablet)	***Purpose***
Sodium Bicarbonate 10 gr (650mg)	Antacid

Indications:

relieves • acid indigestion • heartburn • sour stomach • upset stomach associated with these symptoms

Warnings

Do not use this product if you are on a sodium-restricted diet unless directed by a doctor. 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 maximum dosage for more than 2 weeks, except under the advice and supervision of a physician. As with any drug, if you are pregnant or nursing a baby, seek advice of a health professional before using this product.

Stomach Warning:

TO AVOID SERIOUS INJURY, DO NOT TAKE UNTIL TABLET IS COMPLETELY DISSOLVED. IT IS VERY IMPORTANT NOT TO TAKE THIS PRODUCT WHEN OVERLY FULL FROM FOOD OR DRINK. Consult a doctor if severe stomach pain occurs after taking this product.

Drug Interaction Precaution:

Ask a physician or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Directions:

Adults -Take 1 tablet, dissolved in a glass of water, as needed. • Maximum daily dose for adults up to 60 years of age is 24 tablets. • Maximum daily dose for adults 60 years of age or older is 12 tablets. • Dissolve completely in water before drinking. • DO NOT EXCEED RECOMMENDED DOSE. Not recommended for children.

Other Information:

Each tablet contains: sodium 178 mg (7.74 meq) ·store at room temperature 15°·30°C (59°-86°F) in well-closed containers as defined in the USP.

Inactive Ingredients:

Pregelatinized starch, NF and mineral oil, USP.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

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	650mg
60	43353-041-53
90	43353-041-60
120	43353-041-70
180	43353-041-80
200	43353-041-85
360	43353-041-94

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:

Aphena Pharma Solutions

Cookeville, TN 38506

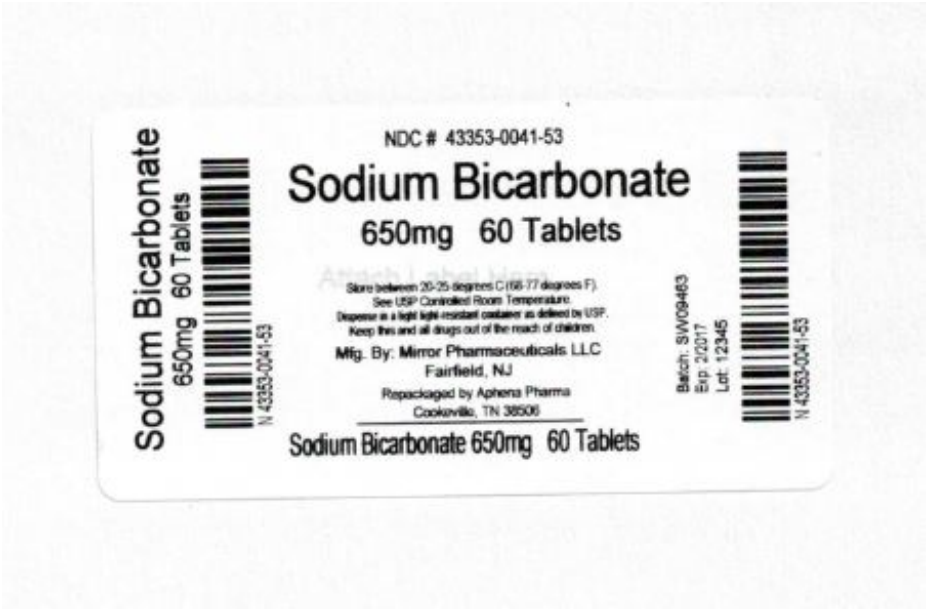
20160628DH

PRINCIPAL DISPLAY PANEL

NDC 43353-041-53

Sodium Bicarbonate Antacid

60 Tablets



SODIUM BICARBONATE

sodium bicarbonate tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43353-041(NDC:64980-182)
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**
STARCH, CORN (UNII: O8232NY3SJ)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	CL;206
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43353-041-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2015	
2	NDC:43353-041-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2015	

3	NDC:43353-041-70	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2015	
4	NDC:43353-041-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2015	
5	NDC:43353-041-85	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2015	
6	NDC:43353-041-94	360 in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/26/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(43353-041)

Revised: 8/2017 Aphena Pharma Solutions - Tennessee, LLC