

SODIUM BICARBONATE - sodium bicarbonate tablet, orally disintegrating

A-S Medication Solutions

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:

HOW SUPPLIED

Product: 50090-3021

NDC: 50090-3021-0 90 TABLET, ORALLY DISINTEGRATING in a BOTTLE

sodium bicarbonate



SODIUM BICARBONATE

sodium bicarbonate tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3021(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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (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:50090-3021-0	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2017	

Marketing Information

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

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3021) , REPACK(50090-3021)

Revised: 7/2018

A-S Medication Solutions