SODIUM BICARBONATE - sodium bicarbonate tablet Rising Pharmaceuticals, Inc.

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 Contract Pharmacal Corp. Hauppauge, NY 11788

Manufactured by:

Lot No.:

Exp. Date:

---PRINCIPAL DISPLAY PANEL---

Rising[®] NDC 64980-294-10

Sodium Bicarbonate 10 gr TABLETS, USP Antacid

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

1000 Tablets

WITHOUT YOUNG CHILDREN. THIS PACKAGE FOR HOUSEHOLDS

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Lot No.:

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SODIUM BICARBONATE

sodium bicarbonate tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64980-294

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII: HN1Z RA3Q20)	SODIUM BICARBONATE	650 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
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			

l	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
		NDC:64980-294- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2017	

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part331	02/01/2017	

Labeler - Rising Pharmaceuticals, Inc. (041241766)

Establishment			
Name	Address	ID/FEI	Business Operations
Contract PharmaCal		968334974	MANUFACTURE(64980-294)

Revised: 1/2023 Rising Pharmaceuticals, Inc.