

SODIUM BICARBONATE 10 GR- sodium bicarbonate tablet
GRAXCELL PHARMACEUTICAL, 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 (650 mg), 70795-1190

Active ingredient (in each tablet)

Sodium bicarbonate 10 gr (650 mg)

Purpose

Antacid

Uses

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 or 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

Drug Interaction Precaution

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**

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

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 meg)**
- 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

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

Drug Facts	
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Manufactured by:
GRAXCELL Pharmaceutical LLC
136 OAK Drive
Syosset, N.Y. 11791

Distributed by:
GRAXCELL Pharmaceutical LLC
130 Knickerbocker Ave
Bohemia, NY 11716
MADE IN USA



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SODIUM BICARBONATE 10 GR

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-1190
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	650 mg

Inactive Ingredients

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

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	11mm
Flavor		Imprint Code	G35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1190-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
2	NDC:70795-1190-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
3	NDC:70795-1190-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
4	NDC:70795-1190-2	200 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/02/2017	

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Establishment

Name	Address	ID/FEI	Business Operations
GRAXCELL PHARMACEUTICAL, LLC		056556923	manufacture(70795-1190)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC