

SODIUM BICARBONATE 5 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 5 gr (325 mg), 70795-1130

Active ingredient (in each tablet)

Sodium bicarbonate 5 gr (325 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

 <p>NDC 70795-1130-5</p> <p>GRAXCELL PHARMACEUTICAL, LLC.</p> <p>Sodium Bicarbonate Sodium Bicarbonate 5 gr (325 mg)</p> <p>Antacid</p> <p>500 Tablets</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient (in each tablet)</td> <td>Purpose</td> </tr> <tr> <td>Sodium Bicarbonate 5 gr (325 mg)</td> <td>Antacid</td> </tr> </table> <p>Uses</p> <p>relieves acid indigestion heartburn sour stomach upset stomach associated with these symptoms</p> <p>Warnings</p> <p>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</p> <p>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.</p> <p>Drug Interaction Precaution: Ask a physician or pharmacist before use if you are presently taking a prescription drug.</p> <p>Antacids may interact with certain prescription drugs</p> <p>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</p> <p>Directions</p> <p>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.</p> <p>Other information</p> <p>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</p> <p>Inactive ingredients Pregelatinized starch, NF and mineral oil, USP</p> <p>Questions or comments? Call toll free 1-888-266-8818</p>	Active ingredient (in each tablet)	Purpose	Sodium Bicarbonate 5 gr (325 mg)	Antacid	<p>Manufactured by: GRAXCELL Pharmaceutical LLC 136 OAK Drive Syosset, N.Y. 11791</p> <p>Distributed by: GRAXCELL Pharmaceutical LLC 130 Knickerbocker Ave Bohemia, NY 11716 MADE IN USA</p>
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GRAXCELL
PHARMACEUTICAL, LLC.

NDC 70795-1130-0

Sodium Bicarbonate

Sodium Bicarbonate 5 gr (325 mg)

Antacid

1000 Tablets

Drug Facts	
Active ingredient (in each tablet) Sodium Bicarbonate 5 gr (325 mg)	Purpose Antacid
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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 5 GR

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-1130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4MONH37)	SODIUM BICARBONATE	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3S)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	G37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1130-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	

2	NDC:70795-1130-0	1000 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(70795-1130)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC