

**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.*

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**Sodium Bicarbonate 5 gr (325 MG), 70795-1180**

***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 70795-1130-0</p> <p><b>Sodium Bicarbonate</b> Sodium Bicarbonate 5 gr (325 mg)</p> <p><b>Antacid</b></p> <p><b>1000 Tablets</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient (in each tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Sodium Bicarbonate 5 gr (325 mg)</td> <td>Antacid</td> </tr> </tbody> </table> <p><b>Uses</b>  <ul style="list-style-type: none"> <li>relieves</li> <li>acid indigestion</li> <li>heartburn</li> <li>sour stomach</li> <li>upset stomach associated with these symptoms</li> </ul> </p> <p><b>Warnings</b>  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.  <b>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</b> Consult a doctor if severe stomach pain occurs after taking this product.  <b>Drug Interaction Precaution:</b> Ask a physician or pharmacist before use if you are presently taking a prescription drug.  <b>Antacids may interact with certain prescription drugs</b>  <b>KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN</b> In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately </p> <p><b>Directions</b>  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.  <b>DO NOT EXCEED RECOMMENDED DOSE</b> Not recommended for children. </p> <p><b>Other information</b>  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><b>Inactive ingredients</b> Pregelatinized starch, NF and mineral oil, USP</p> <p><b>Questions or comments?</b> Call toll free 1-888-266-8818</p>	Active ingredient (in each tablet)	Purpose	Sodium Bicarbonate 5 gr (325 mg)	Antacid	<p><b>Manufactured by:</b>  GRAXCELL Pharmaceutical LLC  136 OAK Drive  Syosset, N.Y. 11791</p> <p><b>Distributed by:</b>  GRAXCELL Pharmaceutical LLC  130 Knickerbocker Ave  Bohemia, NY 11716  MADE IN USA</p>  <p>8 67017 00043 6</p>
Active ingredient (in each tablet)	Purpose					
Sodium Bicarbonate 5 gr (325 mg)	Antacid					

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# SODIUM BICARBONATE 5 GR

sodium bicarbonate tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70795-1180
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	G57
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1180-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
2	NDC:70795-1180-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
3	NDC:70795-1180-1	100 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(70795-1180)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC