

SODIUM BICARBONATE 10 GR. (650 MG)- sodium bicarbonate tablet
Gendose Pharmaceuticals, 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.

GENDOSE - Sodium Bicarbonate 10 gr (650 mg) TABLETS, 77333-831

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
- 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 meq)**
- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients


Pregelatinized starch, NF and mineral oil, USP

NDC 77333-831-10


**Sodium Bicarbonate
10 gr. (650mg) Tablets**

Antacid

UD 100 Tablets (10x10)



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 **GenDose[®]**
Pharmaceuticals

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OTHER INFORMATION:

- each tablet contains: sodium 176mg (7.74meq)
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- Inactive Ingredients: Pregelatinized starch, NF and mineral oil, USP

LB83110X05

SODIUM BICARBONATE 10 GR. (650 MG)

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-831
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4MONH37)	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:77333-831-10	100 in 1 BOX	05/15/2020	
1	NDC:77333-831-25	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/15/2020	

Labeler - Gendose Pharmaceuticals, LLC (080257510)

Registrant - Gendose Pharmaceuticals, LLC (080257510)

Revised: 11/2022

Gendose Pharmaceuticals, LLC