# 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.

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GENDOSE - Sodium Bicarbonate 10 gr (650 mg) TABLETS (77333-827)

### 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 TAKE MORE THAN 24 TABLETS FOR ADULTS UP TO 60 YEARS OF AGE (0R 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.
- 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)

#### **INACTIVE INGREDIENTS**

MICROCRYSTALLINE CELLULOSE, STEARIC ACID, MAGNESIUM STEARATE



# **SODIUM BICARBONATE 10 GR. (650 MG)**

sodium bicarbonate tablet

<b>Product</b>	Inform	ation
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HUMAN OTC DRUG **Item Code (Source)** NDC:77333-827 **Product Type** 

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

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

Inactive Ingredients

mactive ingredients			
Ingredient Name	Strength		
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			

STEARIC ACID (UNII: 4ELV7Z65AP)

### **Product Characteristics**

Color	white	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	S65	
Contains				

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:77333-827-	100 in 1 BOX	03/14/2023		
	1 NDC:77333-827-	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

## Marketing Information

Marketing information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	03/14/2023		

# **Labeler -** Gendose Pharmaceuticals, LLC (080257510)

Revised: 3/2023 Gendose Pharmaceuticals, LLC