

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

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 (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.
- 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

NDC 77333-827-10

Sodium Bicarbonate
10 gr. (650mg) Tablets

Antacid

UD 100 Tablets (10x10)

(01) 0 03 77333 827 10 0

GenDose[®]
Pharmaceuticals

NDC 77333-827-10

Sodium Bicarbonate
10 gr. (650mg) Tablets

Antacid

UD 100 Tablets (10x10)

Drug Facts

Active ingredient (in each tablet)	Purpose
Sodium Bicarbonate 10 gr. (650mg)	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 (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.
- **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 178mg (7.74mEq)
- store at room temperature 15° • 30° C (59° • 86° F)

INACTIVE INGREDIENTS:
Microcrystalline cellulose, stearic acid, magnesium stearate

LB82710X10

SODIUM BICARBONATE 10 GR. (650 MG)

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-827
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-827-10	100 in 1 BOX	03/14/2023	
1	NDC:77333-827-25	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 Drug	M001	03/14/2023	

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

Name	Address	ID/FEI	Business Operations
Neeyaan, LLC		118819217	manufacture(77333-827)

