

SODIUM BICARBONATE- sodium bicarbonate tablet
Ingenus Pharmaceuticals NJ, 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 10 gr (650 mg)

Drug Facts

Active Ingredient (in each tablet)

Sodium bicarbonate 10 gr (650 mg)

Antacid

Indications:

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 and older) in a 24-hour period nor use the 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 advise 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:

Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or

other health professional.

Directions:

- Adults - Take 1 tablet, dissolved in a glass of water, as needed.
- Maximum daily dose for adults upto 60 years of age is 24 tablets.
- Maximum daily dose for adults 60 years of age and 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) in well-closed containers as defined in the USP.

Inactive Ingredients:

Pregelatinized starch, NF and mineral oil, USP.

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.

ingenus

NDC 52682-206-04

SODIUM BICARBONATE

10 gr (650 mg)

Antacid

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

1000 Tablets

Mfd. by Ingenus Pharmaceuticals NJ, LLC

Fairfield, NJ 07004



NDC 52682-206-04

SODIUM BICARBONATE

10 gr (650 mg)

Antacid

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

1000 Tablets

Mfd. by Ingenus Pharmaceuticals NJ, LLC
Fairfield, NJ 07004

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Purpose
Sodium bicarbonate 10 gr (650 mg)..... Antacid

Indications: 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 and older) in a 24-hour period nor use the 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: Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional.

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 and older is 12 tablets. • Dissolve completely in water before drinking. • DO NOT EXCEED RECOMMENDED DOSE. Not recommended for children.

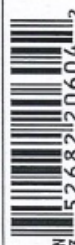
Other information: • each tablet contains: sodium 178 mg (7.74 meq) • store at room temperature 15°-30° C (59°-86° F) in well-closed containers as defined in the USP.

Inactive ingredients: Pregelatinised starch, NF and mineral oil, USP.

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.

Questions? 1-877-748-1970

Rev. 01/2017



Lot. No.:
Exp. Date:

NO VARNISH

0.5" L

SODIUM BICARBONATE

sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52682-206
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	650 mg

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (White)	Score	2 pieces
Shape	ROUND (round)	Size	11mm
Flavor		Imprint Code	CL;206
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52682-206-04	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/24/2011	04/01/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/24/2011	04/01/2025

Labeler - Ingenus Pharmaceuticals NJ, LLC (964680206)

Registrant - Ingenus Pharmaceuticals NJ, LLC (964680206)

Establishment

Name	Address	ID/FEI	Business Operations
Ingenus Pharmaceuticals NJ, LLC		964680206	manufacture(52682-206) , analysis(52682-206) , label(52682-206) , pack(52682-206)

Revised: 12/2022

Ingenus Pharmaceuticals NJ, LLC