

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate BP
Numark Sodium Bicarbonate BP
Boots Sodium Bicarbonate BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Bicarbonate 100%

3. PHARMACEUTICAL FORM

Oral Powder

4.1 Therapeutic indications

1. For use as an antacid for the symptomatic relief of dyspepsia.
2. As an external lotion for the relief of the symptoms of insect bites and sunburn.

4.2 Posology and method of administration

1. Oral: For the relief of the symptoms of dyspepsia, heartburn and indigestion: Adults, the elderly and children aged 12 years and over: Take 1 to 5 g in water 4 to 6 hourly as required. Not recommended for children under 12 years of age.
2. Cutaneous: As an external lotion: Dissolve one 5 ml spoonful in a pint of warm water. Apply with lint or cotton wool.

4.3 Contraindications

Contraindicated in patients with metabolic or respiratory alkalosis, hypocalcaemia, or

hypochlorhydria.

Not to be taken by children under 12 years old.

It should be used with extreme caution in patients with congestive heart failure, renal impairment, cirrhosis of the liver, or hypertension, or to patients receiving corticosteroids.

Hypersensitivity to sodium bicarbonate.

4.4 Special warnings and precautions for use

Keep all medicines away from children.

Caution should be exercised in patients who are on Sodium restricted diets and those with cardiac disease, hypertension, renal or hepatic impairment.

This medicine contains 1.02g sodium (main component of cooking/table salt) in each 5ml spoonful of sodium bicarbonate. This is equivalent to 51% of the WHO recommended maximum daily intake of 2 g for an adult.

A physician should be consulted if the patient is receiving other medications before taking this product. If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of a number of drugs may be reduced or increased by the alkalisation of the urine (e.g. aspirin or diflunisal) and reduction in gastric pH brought about by sodium bicarbonate.

The following drugs are reported to be susceptible to inactivation on mixing with sodium bicarbonate solution: adrenaline hydrochloride, benzyl penicillin potassium, carmustine, glycopyrronium bromide, isoprenaline hydrochloride, and suxamethonium chloride.

Sodium-containing preparations should be avoided by patients on lithium because sodium is preferentially absorbed by the kidney resulting in increased lithium excretion and reduced plasma levels.

As a precaution for antacids, in order to minimise the risk of interactions affecting pharmacokinetics of concomitantly administered products, drug administrations should be separated by approximately 2 to 3 hours.

Sodium bicarbonate reduces the absorption of a number of other drugs taken concomitantly.

These include ACE inhibitors (captopril, enalapril, and fosinopril), antibacterials and antifungals (azithromycin, cefaclor, cefpodoxime, isoniazid, itraconazole, rifampicin, tetracyclines, ketoconazole and the quinolone group of antibacterials); antivirals (atazanavir, fosamprenavir, tipranavir); antihistamines (fexofenadine); bisphosphonates, corticosteroids (deflazacort); digoxin, dipyridamole, antiepileptics (gabapentin and phenytoin), ulcer healing drugs (lansoprazole); levothyroxine, mycophenolate, lipid regulating drugs (rosuvastatin); antipsychotics (sulpiride, phenothiazines), chloroquine, hydrochloroquine, and penicillamine. Antacids should be avoided with nilotinib.

Antacids possibly reduce absorption of bile acids

4.6 Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Bicarbonate of Soda (Sodium Bicarbonate BP) on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.

Animal studies are insufficient with respect to effects on pregnancy, embryonal foetal development, parturition and postnatal development. The potential risk for humans is unknown.

Caution should be exercised, when prescribing to pregnant women.

Sodium bicarbonate should not be taken in pregnancy or if breastfeeding unless advised by a doctor to do so.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Administration by mouth can cause stomach cramps and flatulence.

This medicine may cause abdominal cramps and flatulence. Excessive administration may lead to metabolic alkalosis, especially in patients with impaired renal function.

Additional undesirable effects associated with oral use of sodium bicarbonate include possible increase in blood pressure, exacerbation of hyperkalaemia, and fluid retention and pulmonary oedema may be caused in those at risk.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.yellowcard.mhra.gov.uk.

4.9 Overdose

Excessive administration of bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, shortness of breath, muscle weakness and irregular heart beat. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients.

Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality.

Treatment of metabolic alkalosis and hypernatraemia is by correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium ions may be of particular importance.

5.1 Pharmacodynamic properties

Antacids with sodium bicarbonate A02A H

Sodium bicarbonate is used as an antacid in relief of the symptoms of dyspepsia, heartburn and indigestion caused by excess gastrointestinal acid.

Solutions of sodium bicarbonate when applied topically act to relieve the symptoms of insect bites and sunburn.

5.2 Pharmacokinetic Properties

Not applicable

5.3 Preclinical Safety Data

Never undertaken by Abdine Limited. This product was granted a 'Licence as of Right' some 25 years ago.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None

6.3 Shelf life

As packaged for sale: Three years

As reconstituted for use: Thirty minutes

After first opening the container: One month

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A spirally wound, varnished, cardboard tub with a press-fit lid or polypropylene jar and cap containing 100g, 150g, 200g, 250g, 300g or 500g of sodium bicarbonate.

6.6 Instruction for use and handling

Take 1 to 5g in water.

7. MARKETING AUTHORISATION HOLDER

Bell Sons & Co (Druggists) Ltd

Gifford House

Slaidburn Crescent

Southport

Merseyside

PR9 9AL

UK

8. MARKETING AUTHORISATION NUMBER

PL 03105/0067

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th February 1999

10 DATE OF REVISION OF THE TEXT

10/11/2022