

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Sodium Bicarbonate B.P.

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Sodium Bicarbonate B.P. 100% w/w

## **3 PHARMACEUTICAL FORM**

Powder.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

- 1) For the relief of the symptoms of dyspepsia, heartburn and indigestion.
- 2) As an external lotion for relief of the symptoms of insect bites and sunburn.

### **4.2 Posology and method of administration**

#### **Posology:**

1) For the relief of the symptoms of dyspepsia, heartburn and indigestion Adults, elderly and children over 12 years:

One level 5ml spoonful dissolved in warm water, to be taken up to 4 times a day.

Not to be taken by children under 12 years old.

2) To use externally as a lotion:

Dissolve one 5ml spoonful in a pint of warm water. Apply with lint or cotton wool.

Method of administration

- 1) Oral.
- 2) Cutaneous.

### **4.3 Contraindications**

For oral use:

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

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.

Not to be taken by children under 12 years old. Hypersensitivity to sodium bicarbonate

### **4.4 Special warnings and precautions for use**

Keep all medicines away from children.

Sodium bicarbonate should be avoided in patients on a restricted sodium diet.

### **4.5 Interaction with other medicinal products and other forms of interaction**

For oral use:

The effects of a number of drugs may be reduced or increased by the alkalinisation 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 excretion of lithium (reduced plasma concentration).

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 Fertility, pregnancy and lactation**

##### **Pregnancy**

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

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

##### **Breast-feeding**

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

#### **4.7 Effects on ability to drive and use machines**

Sodium Bicarbonate B.P. has no or negligible influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Administration by mouth can cause stomach cramps and flatulence. 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 Yellow Card Scheme.

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **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 heartbeat. 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 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Antacids with sodium bicarbonate, ATC code: 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**

No information available

### **5.3 Preclinical safety data**

None known.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Incompatibilities

Sodium bicarbonate is incompatible with acids, acidic salts, and many alkaloidal salts.

Sodium bicarbonate solution should not be mixed with calcium or magnesium salts, cisplatin, dobutamine hydrochloride, labetalol hydrochloride, oxytetracycline hydrochloride, as insoluble precipitates may result.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

None

### 6.5 Nature and contents of container

| NATURE   | CONTENTS               |
|--|------------------------|
| A. Sodium bicarbonate BP is packed in a sealed clear LDPE bag, packed in a white HDPE container with a white LDPE push fit tamper evident cap. | 100gm, 200gm or 500gm. |
| B. Foodgrade paper bag in a printed cardboard carton   | 200gm.                 |

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

None stated.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Cox Pharmaceutical Ltd.

Elscot House

Arcadia Avenue,

London, N3 2JU

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 42671/0007

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

15/05/90

**10 DATE OF REVISION OF THE TEXT**

28/02/2020