SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium bicarbonate 84mg/ml oral solution

Bidex 84mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of oral solution contains 84mg of sodium bicarbonate (equivalent to 1 mmol/ml sodium bicarbonate). For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Clear colourless solution, free of visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium bicarbonate is indicated in adults (including elderly) for:

- the treatment of metabolic acidosis arising from a variety of disorders. The dosage must be calculated on an individual basis and is dependent on the acid-base balance and electrolyte status of the patient.
- the short-term symptomatic treatment of mild or transient dyspepsia.

4.2 Posology and method of administration

Posology

Adults (including elderly):

Metabolic acidosis: dosage is calculated on an individual basis and is dependent on acid-base balance and electrolyte status.

Dyspepsia: Doses of 12 – 60ml (approximately 1 – 5g) every 4 – 6 hours as required.

Paediatric population:

The efficacy of sodium bicarbonate in children under 18 years of age has not been established. No data are available.

Method of administration

For oral use.

Measuring oral syringe

The required dose should be drawn from the container into the graduated oral syringe using the oral syringe adaptor (see section 6.6).

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Metabolic or respiratory alkalosis
- Hypokalaemia
- Hypernatraemia
- Hypocalcaemia
- Hypochlorhydria
- Patients on a low sodium diet

4.4 Special warnings and precautions for use

Overtreatment with bicarbonate must be avoided. Frequent monitoring of serum electrolytes and acid-base status is essential. In patients with moderate and advanced chronic renal disease, the association between serum bicarbonate concentration and all-cause mortality is U-shaped. The lowest mortality rate is seen in patients with serum bicarbonate concentration in the range of 26-29 mmol/l. The highest mortality rate is observed among patients with serum bicarbonate levels of < 22 mmol/l but an increase in mortality is also seen in patients with serum bicarbonate levels of > 29 mmol/l.

Sodium bicarbonate should be given extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension, eclampsia, aldosteronism, or other conditions associated with sodium retention.

Do not take if you are hypersensitive to sodium bicarbonate.

Consult your doctor or pharmacist if symptoms persist after 7 days.

This medicine can mask the symptoms of stomach cancer or ulcer.

Since the efficacy of sodium bicarbonate in children under 18 years of age has not been established Sodium bicarbonate 84mg/ml oral solution is not recommended in children.

This medicinal product contains 23mg of sodium per ml, equivalent to 1.15% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 414% of the WHO recommended maximum daily intake for sodium.

Sodium bicarbonate 84mg/ml oral solution is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

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 alkalinisation of the urine (e.g. aspirin or diflunisal) and changes in gastric pH brought about by sodium bicarbonate.

In particular cases elimination of weak acids and bases may be affected by sodium hydrogen carbonate treatment via an increase of the pH in urine. This might for example apply to sympathomimetics, anticholinergics, tricyclic antidepressants, barbiturates, H2-blockers, captopril and quinidine.

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.

Large amounts of milk or calcium containing products should not be taken whilst taking this medicine. Such administration may result in milk-alkali syndrome.

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, hydroxychloroquine, and penicillamine. Antacids should be avoided with nilotinib.

Functional interactions with gluco- and mineralocorticoids, androgens and diuretics associated with increased potassium excretion may occur.

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 fetal development, parturition and postnatal development. The potential risk for humans is unknown. Sodium bicarbonate should not be taken during pregnancy unless advised by a doctor to do so.

Breast-feeding

The effects of sodium administration during breastfeeding are not known. Sodium bicarbonate should not be taken if breast-feeding unless advised by a doctor to do so.

Fertility

The potential risks of sodium on fertility are not known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

General adverse effects of sodium bicarbonate are as follows. The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

MedDRA System Organ Class	**Adverse reaction**
Metabolism and nutrition disorders	
Frequency not known	Alkalosis on prolonged use Fluid retention Hypokalaemia may be exacerbated Metabolic alkalosis Loss of appetite (continuing)

Psychiatric disorders	
Frequency not known	Mood or mental changes Nervousness or restlessness
Nervous system disorders	
Frequency not known	Headache (continuing) Dizziness
Vascular disorders	
Frequency not known	Hypertension Slow breathing Breathing difficulties Fluid on the lungs
Respiratory, thoracic and mediastinal disorders	
Frequency not known	Pulmonary oedema
Gastrointestinal disorders	
Frequency not known	Abdominal discomfort Abdominal distention Flatulence Spontaneous stomach rupture Nausea Vomiting Unpleasant taste
Skin and subcutaneous tissue disorders	
Frequency not known	Swelling of feet or lower legs
Renal and urinary disorders	
Frequency not known	Frequent urge to urinate Promotion of renal urolithiasis (formation of calcium or magnesium phosphate calculi) upon prolonged use.
General disorders and administration site conditions	
Frequency not known	Extreme irritability Unusual tiredness or weakness Muscle spasms or cramps

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.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 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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary tract and metabolism; Drugs for acid related disorders; Antacids; Antacids with sodium bicarbonate, ATC code: A02AH

Mechanism of action

Sodium bicarbonate is used for a variety of therapeutic purposes including the correction of metabolic acidosis and as an antacid for the treatment of dyspepsia. Sodium bicarbonate causes neutralisation of gastric acid with the production of carbon dioxide.

Pharmacodynamic effects

Sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses clinical manifestations of metabolic acidosis.

5.2 Pharmacokinetic properties

Absorption

Sodium bicarbonate is readily absorbed from the gastro-intestinal tract.

Sodium bicarbonate exists as a sodium ion and bicarbonate ion within Sodium bicarbonate 84mg/ml oral solution 1.25mg, 2.5mg. Once orally administered, the bicarbonate ion readily binds to hydrochloric acid in the stomach to form sodium chloride, carbon dioxide and water.

Bicarbonate ions which do not react with hydrochloric acid within the stomach are readily emptied into the duodenum via the pylorus. Bicarbonate ions are then readily absorbed through the small intestine where they enter general circulation. A linear dose dependent relationship between sodium bicarbonate supplementation and serum bicarbonate levels have been shown in CKD patients with metabolic acidosis.

Distribution

Sodium bicarbonate is present in all body fluids. Sodium bicarbonate causes neutralization of gastric acid with the production of carbon dioxide.

The bicarbonate ion is freely soluble in the blood stream and readily crosses the blood brain barrier. The site of action of bicarbonate ions with respect to metabolic acidosis is the blood stream.

Biotransformation

The bicarbonate ion is a simple electrolyte and is therefore not hepatically metabolised but rather eliminated from the body via excretion.

Elimination

Any bicarbonate not involved in the gastric acid neutralisation reaction is absorbed. The bicarbonate ion is excreted through various bodily pathways. Firstly, sodium bicarbonate is excreted via the pulmonary system. This involves the bicarbonate ion binding with a free hydrogen ion to form carbonic acid which is then broken down into carbon dioxide and water in the presence of carbonic anhydrase and excreted through the lungs. Bicarbonate ions readily pass through the renal cortex and are eliminated via urine.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 1 year.
After first opening: 7 days.

6.4 Special precautions for storage

Store below 25°C. Do not refrigerate or freeze. Do not use if crystals are observed in the product.

6.5 Nature and contents of container

Bottle: 100ml Amber PET bottle

Closure: White PP tamper evident child resistant closure with EPE liner

Dosing device: 20ml CE marked measuring oral syringe.

6.6 Special precautions for disposal

The product may be administered using an oral syringe. The instructions for using the oral syringe are as follows:

The required dose should be drawn from the container into the graduated oral syringe provided using the oral syringe adaptor (see detailed instructions below). The oral syringe should be held into the mouth of the patient, and the contents of the oral syringe should then be ejected into the mouth and swallowed.

a) Open the bottle: press the cap and turn it anticlockwise (figure a)

b) Separate the adaptor from the oral syringe. Insert the adaptor into the bottle neck.
Ensure it fits well (figure b). Take the oral syringe and put it in the adaptor opening. Turn the bottle upside down (figure c).

c) Fill the oral syringe with a small amount of solution by pulling the piston down, then push the piston up in order to remove any possible bubble. Pull the piston down to the graduation mark corresponding to the required dosage in millilitres (ml) (figure d).

d) Turn the bottle the right way up. Remove the oral syringe from the adaptor. Empty the contents of the oral syringe into the patient's mouth by pushing the piston to the bottom of the oral syringe (figure e). Close the bottle with the plastic screw cap.

Figure a

Figure b

Figure c

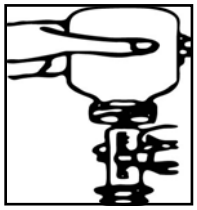

Figure d

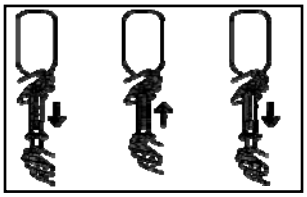

Figure e

- Drain any remaining solution in the oral syringe and wash it with water after use. Store the oral syringe in a clean and dry place.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 55612/0023

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/03/2025

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