SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 8.4% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL solution for injection contains 84 mg sodium bicarbonate.

Excipients with known effect

Each mL solution for injection contains 23.00 mg sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless aqueous solution, free from visible particles
pH 7.0 – 8.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Bicarbonate Injection is indicated in adults and children for:

- Correction of metabolic acidosis associated with cardiac arrest in patients with pre-existing metabolic acidosis
- Cardiac arrest associated with hyperkalaemia with pre-existing metabolic acidosis
- Life threatening hyperkalaemia with pre-existing metabolic acidosis
- Tricyclic antidepressant overdose

Sodium bicarbonate should only be used after other resuscitative measures such as cardiac compression, ventilation, adrenaline and antiarrhythmic agents have been attempted.
In neonates, Sodium Bicarbonate Injection is indicated for:

- Correction of metabolic acidosis associated with cardiac arrest in patients with pre-existing metabolic acidosis
- Cardiac arrest associated with hyperkalaemia with pre-existing metabolic acidosis
- Life threatening hyperkalaemia with pre-existing metabolic acidosis

No benefits have been demonstrated from the routine use of sodium bicarbonate in resuscitation of neonates. In neonates, sodium bicarbonate is recommended in

resuscitation only in cases of prolonged cardiac arrest, irresponsive to other therapy, after establishment of adequate ventilation and circulation.

4.2 Posology and method of administration

Posology
The posology depends largely on the extent of the acid-base imbalance. This should be checked regularly.
Adults:
The usual dose is 1 mmol/kg (1 mL/kg 8.4% solution) followed by 0.5 mmol/kg (0.5 mL/kg 8.4% solution) given at 10-minute intervals.
Paediatric population:
The usual dose is 1 mmol/kg by slow iv injection (1 mL/kg 8.4% solution)
In premature infants and neonates, the 8.4% solution should be diluted 1:1 with 5% w/v dextrose.
Elderly:
As for adults.
Method of administration
For intravenous administration only.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Conditions where sodium intake is restricted (e.g. renal failure, hypertension, oedema, congestive heart failure)
- Respiratory and metabolic alkalosis
- Hypoventilation
- Coexistent potassium depletion or chloride depletion, hypocalcaemia and hypernatraemia

4.4 Special warnings and precautions for use

Sodium bicarbonate should not be administered in the following situations unless it has been established that its expected benefits clearly outweigh potential risks:

- respiratory acidosis

- hypocalcaemia

- increased serum osmolarity,

- further in all situations where sodium intake must be restricted like cardiac insufficiency, oedema, hypertension, eclampsia, severe renal insufficiency.

Whenever sodium bicarbonate is used intravenously, arterial blood gas analyses, in particular arterial/venous blood pH and carbon dioxide levels, should be performed

before and during the course of treatment to minimise the possibility of overdose and resultant alkalosis.

In long-term therapy, care is essential to prevent the risk of overdose and alkalosis. Therefore, repeat administrations of fractional doses, or an infusion, should be given while regularly monitoring the acid-base balance and electrolytes. As soon as the most severe symptoms are under control, the dose and frequency of administration must be reduced until normal values have been restored.

Whenever respiratory acidosis is concomitant with metabolic acidosis, both pulmonary ventilation and perfusion must be adequately supported to get rid of excess CO_2.

Administration of sodium bicarbonate to a patient with inadequate minute ventilation can cause worsening of the acidosis.

The treatment of metabolic acidosis must, if possible, be combined with concurrent treatment to combat the primary cause of the acidosis, for example the administration of insulin in uncomplicated diabetes, or blood volume restoration in shock.

There is no evidence to support the use of bicarbonate therapy in the treatment of hypoperfusion-induced lactic acidaemia associated with sepsis.

Accidental extravascular injection of hypertonic solutions may cause vascular irritation or sloughing. The use of scalp veins should be avoided.

Excipient

This medicinal product contains 23.00 mg sodium per mL, equivalent to 1.15% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be used when administering sodium ions to patients receiving corticosteroids or corticotrophin.

Urinary alkalisation will increase the renal clearance of medicinal products which are acid in nature e.g. tetracyclines, especially doxycycline, acetylsalicylic acid, chlorpropamide, lithium, methenamine. It increases the half-life and duration of action of basic active substances such as quinidine, amphetamines, ephedrine, pseudoephedrine, memantine and flecainide. Sodium bicarbonate is known to increase renal tubular reabsorption of mecamylamine causing hypotension.

Hypochloraemic alkalosis may occur if sodium bicarbonate is used in conjunction with potassium depleting diuretics such as bumetamide, ethacrynic acid, frusemide and thiazides.

Concurrent use in patients taking potassium supplements may reduce serum potassium concentration by promoting an intracellular ion shift.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of sodium bicarbonate in pregnant women. Sodium bicarbonate should not be used during pregnancy unless the clinical condition of the woman requires treatment with sodium bicarbonate.

It is unknown whether sodium bicarbonate/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from sodium bicarbonate therapy. A risk to the newborns/infants cannot be excluded.

4.7 Effects on ability to drive and use machines

Not applicable; this preparation is intended for use only in emergencies.

4.8 Undesirable effects

Metabolism and nutrition disorders

Alkalosis, hypokalaemia, hypernatraemia, hyperosmolarity, hypocalcaemia, hypoglycaemia, paradoxical intracellular acidosis.

Nervous system disorders

Intracranial haemorrhage (in neonates), hyperirritability or tetany.

Cardiac disorders

Deterioration of haemodynamic status associated with volume overload.

General disorders and administration site conditions

Extravasation.

Incorrect administration (intra-arterial, paravenous) may cause tissue necrosis.

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

Symptoms

Metabolic alkalosis accompanied by compensatory hyperventilation, paradoxical acidosis of the cerebrospinal fluid, severe hypokalaemia, hyperirritability and tetany.

Treatment

Discontinue the administration of sodium bicarbonate, rebreathe expired air or, if more severe administer calcium gluconate especially if tetany is present. In severe

alkalosis, an infusion of 2.14% ammonium chloride is recommended, except in patients with pe-existing hepatic disease. If hypokalaemia is present administer potassium chloride.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolyte solution, ATC code: B05XA02
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

Sodium bicarbonate is eliminated principally in the urine and effectively alkalises it.

5.3 Preclinical safety data

Not applicable since sodium bicarbonate has been used in clinical practice for many years and its effects in man are well known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Water for Injections

6.2 Incompatibilities

The addition of sodium bicarbonate to parenteral solutions containing calcium should be avoided except where compatibility has been previously established; precipitation or haze may result, should this occur, the solution should not be used.

Administration of sodium bicarbonate is incompatible with allopurinol sodium, amiodarone hydrochloride, anileridine, ascorbic acid injection, carmustine, cefamandole, cefotaxime, codeine phosphate, dobutamine hydrochloride, dopamine hydrochloride, doxapram, epinephrine hydrochloride, esmolol, fenoldopam mesylate, glycopyrrolate, hydromorphone hydrochloride, idarubicin hydrochloride, inamrinone lactate, isoproterenol hydrochloride, labetalol hydrochloride, levofloxacin, levophanon tatrate, magnesium sulfate, methadone, metoclopramide hydrochloride,

morphine sulfate, moxalactam, nicardipine hydrochloride, norepinephrine bitartrate, ondasetron hydrochloride, oxytetracycline, pentazocine lactate, sargramostin, secobarbital, streptomycin sulfate, succinylcholine chloride, tetracycline, ticarcillin disodium/clavulanate potassium, trimethaphan, tubocurarine and vinorelbine tartrate.

It is also incompatible with the solutions of: alcohol 5% in dextrose 5%, dextrose 5% in lactated Ringer's injection, ionosol(R) B in invert sugar 10%, ionosol(R) D, modified in invert sugar 10%, isonosol(R) D in invert sugar 10%, and ionosol(R) G in invert sugar 10%.

6.3 Shelf life

3 years

Shelf life after dilution

Chemical and physical in-use stability has been demonstrated for Sodium Bicarbonate 8.4% w/v diluted 1:1 with Dextrose 5% w/v in an infusion bag, polypropylene syringe or glass syringe at 2-8°C and 25°C for 48 hours.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless the dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Colourless type I glass ampoule containing 10 mL solution for injection.

Pack size

10 x 10 mL ampoules

6.6 Special precautions for disposal

Discard container and any unused content after use.

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

7 MARKETING AUTHORISATION HOLDER

Torbay Pharmaceuticals Limited
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Paignton
Devon
TQ4 7FG
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 56021/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/07/2025

10 DATE OF REVISION OF THE TEXT

27/11/2025