

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate Injection BP Minijet 8.4% w/v, Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium bicarbonate 84 mg in 1 ml.

840 mg/10 ml in a prefilled syringe.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution.

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 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, unresponsive 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. Administration is via slow intravenous injection.

For intravenous administration only.

Adults:

The usual dose is 1 mmol/kg (1ml/kg 8.4% solution) followed by 0.5mmol/kg (0.5ml/kg 8.4% solution) given at 10 minute intervals.

Children:

The usual dose is 1mmol/kg by slow iv injection. (1ml/kg 8.4% solution)

In premature infants and neonates, the 8.4% solution should be diluted 1:1 with 5% dextrose.

Elderly:

As for adults.

4.3 Contraindications

Administration of sodium bicarbonate is contraindicated in patients

Conditions where sodium intake is restricted (e.g. renal failure, hypertension, oedema, congestive heart failure)

- Patients with hypoventilation (risk of worsening of acidosis)
- Metabolic or respiratory alkalosis
- Patients with a history of urinary calculi
- Patients with coexistent potassium depletion or chloride depletion, hypocalcaemia and hypernatraemia.

4.4 Special warnings and precautions for use

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 overdosage and resultant alkalosis.

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

Whenever respiratory acidosis is concomitant with metabolic acidosis, both pulmonary ventilation and perfusion must be adequately supported to get rid of excess CO₂. 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.

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.

Large quantities of sodium may potentially be administered with bicarbonate. Each 84 mg/ml injection contains 22.9 mg of Na⁺/ml.

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

4.5 Interaction with other medicinal products and other forms of interactions

Caution should be used when administering sodium ions to patients receiving corticosteroids or corticotrophins as an interaction may occur.

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 drugs 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 shift.

4.6 Fertility, pregnancy and lactation

Safe use in pregnancy has not been established. The use of any drug in pregnant or lactating women requires that the expected benefit be carefully weighed against the possible risk to the mother and child.

Patients requiring i.v. sodium bicarbonate are unlikely to be fit enough to breast feed.

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, hypernatremia, hyperosmolarity, hypocalcemia, hypoglycemia, paradoxical intracellular acidosis.

Cardiac disorder:

Deterioration of hemodynamic status associated with volume overload.

Nervous system disorders:

Intracranial hemorrhage (in neonates), hyperirritability or tetany.

General disorders and administration site condition: Extravasation.

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

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 pre-existing hepatic disease, however expert advice should be sought in this circumstance. If hypokalaemia is present administer potassium chloride.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 alkalisates 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

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.

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%, ionosol(R) D in invert sugar 10%, and ionosol(R) G in invert sugar 10%.

In the absence of compatible studies sodium bicarbonate 8.4% solution for injection must not be mixed with other medicinal products.

6.3 Shelf life

3 years. The product should be used immediately after opening. Discard any unused portion.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

The solution is contained in a 10 ml Type I glass syringe with a polycarbonate Luer lock connector, polystyrene plunger rod and latex-free bromobutyl rubber plunger stopper.

One syringe per carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only.

Discard any remaining contents.

The container is specifically designed for use with the IMS Minijet Injector.

7 MARKETING AUTHORISATION HOLDER

DLRC Pharma Services Limited
Chesterfield House
Clonmannon
Ashford
Wicklow
Ireland

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th September 1977

Date of last renewal: 8th September 2007

10 DATE OF REVISION OF THE TEXT

May 2019