

DATA SHEET

NAME OF MEDICINE

Sodium Bicarbonate Injection 4.2g/50mL MIN-I-JET

PRESENTATION

Sodium bicarbonate, NaHCO₃, is a white, odourless, crystalline powder. Sodium Bicarbonate Injection is a sterile aqueous solution of sodium bicarbonate 8.4% w/v (1 mmol/mL) of both sodium and bicarbonate ions. The pH of the solution is approximately 7.8.

USES

ACTIONS

Bicarbonate in the body acts as a buffer. Excess hydrogen ions react with bicarbonate resulting in the formation of carbon dioxide and water. The former is excreted from the lungs and the latter from the kidneys.

Sodium bicarbonate therapy therefore, by increasing plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses clinical manifestations of metabolic acidosis. It is excreted mainly in the urine which it makes alkaline.

INDICATIONS

For the correction of documented metabolic acidosis caused by cardiac arrest after standard resuscitation measures have been instituted. Adequate ventilation must be maintained.

DOSAGE AND ADMINISTRATION

The dose of sodium bicarbonate to be used for the treatment of metabolic acidosis depends on the requirements of the individual patient as determined by blood gas analyses and pH testing both before and during treatment.

Adults

The usual dose is 1 mmol/kg (1 mL/kg) followed by 0.5 mmol/kg (0.5 mL/kg) given at 10 minute intervals.

Children

The usual dose is 1 mmol/kg (1 mL/kg) given by slow intravenous injection. Up to 2 years of age, the solution should be diluted with an equal amount of 5% dextrose and it is recommended that the rate of IV administration does not exceed 8 mL/kg/day.

Elderly

As for adults.

CONTRAINDICATIONS

The administration of sodium bicarbonate is contraindicated in patients with renal failure, metabolic or respiratory alkalosis, hypertension, oedema, congestive cardiac failure, hypoventilation, chloride depletion, hypernatraemia, hypocalcaemia, coexistent potassium depletion or a history of urinary calculi.

WARNINGS AND PRECAUTIONS

For intravenous administration only.

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 minimize the possibility of overdosage and resultant alkalosis.

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

Rapid injection (10mL/minute) of sodium bicarbonate solutions in children up to 2 years of age may produce hypernatraemia, decreased CSF pressure and possible intracranial haemorrhage. In emergency situations, such as cardiac arrest, the risk of rapid infusion of the drug must be weighed against the potential for death from acidosis. Also, administration of this drug to children undergoing cardiopulmonary resuscitation may worsen respiratory acidosis.

To minimise the risks of pre-existing hypokalaemia and/or hypocalcaemia, these electrolyte disturbances should be corrected prior to initiation of, or concomitantly with, sodium bicarbonate therapy.

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

The sodium bicarbonate is in a single use MIN-I-JET prefilled syringe. Once the unit is assembled and used, any remaining portion of the solution must be discarded with the entire unit.

Use in pregnancy

Safe use in pregnancy has not been established. The benefits of using the product should be weighed against possible risks to the foetus.

Use in lactation

Safe use in breastfeeding has not been established.

Interactions with other drugs

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

Urinary alkalinisation will increase the renal clearance of tetracyclines, especially doxycycline, but it will increase the half life and duration of action of basic drugs such as quinidine, amphetamines, ephedrine and pseudoephedrine.

Hypochloreaemic 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.

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 be immediately discarded.

Effects on laboratory tests

The high urinary alkalinity sometimes produced by sodium bicarbonate may cause a false-positive Labstix test for urinary protein.

ADVERSE EFFECTS

Alkalosis and/or hypokalaemia may ensue as a result of prolonged use or overcorrection of the bicarbonate deficit. Hyperirritability or tetany may occur, caused by rapid shifts of free ionised calcium or due to serum protein alterations arising from the pH changes.

Accidental extravasation of hypertonic sodium bicarbonate solutions has been reported to cause chemical cellulitis and ulceration.

OVERDOSAGE

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

Overdosage may also be accompanied by compensatory hyperventilation and paradoxical acidosis of the cerebrospinal fluid.

Management: should alkalosis result, the bicarbonate should be stopped and the patient managed according to the degree of alkalosis present. Rebreathing expired air may help but if more severe, calcium gluconate may be necessary, particularly if tetany is present. In severe alkalosis, an infusion of 2.14% ammonium chloride is recommended except in patients with pre-existing hepatic disease. If hypokalaemia is present, administer potassium chloride.

Contact the Poisons Information Centre on 131 126 in Australia or 0880 764 766 in New Zealand for further advice on overdose management.

PHARMACEUTICAL PRESENTATION

Store below 25°C. Protect from light.

MEDICINE CLASSIFICATION

General Sales Medicine.

PACKAGE QUANTITIES

Sodium bicarbonate injection is available in a single use prefilled MIN-I-JET syringe containing 8.4% w/v sodium bicarbonate (1 mmol/mL) in 50 mL.

FURTHER INFORMATION

Nil

NAMES AND ADDRESSES

Manufactured by:
International Medication Systems, Limited
1886 Santa Anita Avenue,
South El Monte 91733, California
USA

Distributed in Australia by:
CSL Limited, ABN 99 051 588 348
45 Poplar Road,
Parkville 3052, Victoria
AUSTRALIA

Distributed in New Zealand by:
CSL (NZ) Limited
666 Great South Road
Penrose, Auckland
NEW ZEALAND

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