

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 8.4% w/v Injection

2. Qualitative and Quantitative Composition

Sodium Bicarbonate
For excipients see 6.1

3. Pharmaceutical Form

Solution for Injection

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the correction of metabolic acidosis associated with cardiac arrest after other resuscitative measures, such as cardiac compression, ventilation, adrenaline and anti arrhythmic agents have been used.

4.2. Posology and Method of Administration

For intravenous administration only.

Adults and children over 12 years

The usual dose is 1mmol/kg (2 ml/kg 4.2% solution or 1ml/kg 8.4% solution)
Followed by 0.5mmol/kg (1ml/kg 4.2% solution or 0.5ml/kg 8.4% solution)
given at 10 minute intervals.

Children under 12 years

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

In premature infants and neonates, the 4.2% solution should be used or the 8.4% solution should be diluted 1:1 with 5% dextrose.

Elderly

As for adults

4.3. Contra-indications

Sodium Bicarbonate intravenous infusion is contra-indicated in cases of respiratory and metabolic alkalosis, hypoventilation, hypernatraemia, urinary calculi, potassium and chloride depletion, hypocalcaemia and in situations where supply of sodium is contra-indicated such as cardiac insufficiency, oedema, hypertension, eclampsia, renal impairment.

4.4. Special Warnings and Precautions for Use

Whenever sodium bicarbonate is used intravenously, arterial blood gas analysis, 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 off excess CO₂

4.5. Interactions with other Medicaments and other forms of Interaction

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

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

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.

Lithium excretion increased with reduced plasma lithium concentration.

4.6. 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 mother and child.

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

Alkalosis and/or hypokalaemia may ensue as a result of prolonged use or over-correction 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 pH changes.

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. 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 alkalises it.

5.3. Preclinical Safety Data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Nitrogen

6.2. Incompatibilities

Sodium Bicarbonate Injection must not be administered simultaneously with solutions containing Calcium, Magnesium and Phosphate.

6.3. Shelf Life

2 years.

6.4. Special Precautions for Storage

Do not store above 25°C. Store in the original container.

6.5. Nature and Contents of Container

Type 1 clear glass prefilled syringes 10 ml stopper rubber PH 50/701C with tip cap rubber W1 883, containing 8.4% w/v Sodium Bicarbonate BP in Water for Injections.

6.6. Instruction for Use/Handling

No needle is provided with this syringe.

Discard any unused solution at the end of the session in the appropriate manner.

Don't use the product if the packaging is damaged.

7 MARKETING AUTHORISATION HOLDER

Aurum Pharmaceuticals Ltd.
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8. Marketing Authorisation Number

PL 12064/0052

9. Date of First Authorisation/Renewal of Authorisation

6 September 2001

10. Date of (Partial) Revision of the Text

25/03/2009