pharmaniaga®

Sodium Bicarbonate 8.4% w/v Injection

DESCRIPTION
A clear and colourless solution. Single dose container.

COMPOSITION:
Each 10 ml contains:
Sodium Ion 10mEq
Bicarbonate Ion 10mEq
Other ingredients include Sodium Edetate 0.1mg/mL.

PHARMACODYNAMICS
The pH of plasma is normally maintained at around 7.4, the plasma-bicarbonate concentration in the range 22 to 30mmol per litre and the partial pressure of carbon dioxide (pCO_2) at 40 mm Hg by means of respiratory, renal and buffering mechanisms.

The most important buffer system is the bicarbonate-carbonic acid system, which operates on a compensatory basis in the regulation of the acid- base balance.

PHARMACOKINETICS
Sodium and bicarbonate ions are excreted in the urine while carbon dioxide formed is excreted via the lungs.

Absorption from subcutaneous administration is unpredictable. This route of administration is not generally recommended except in those cases where the intravenous route is not applicable.

Carbonic acid, the principal acidic end product of metabolism, exists in a dynamic equilibrium with carbon dioxide and water in body fluids, which in turn are in equilibrium with bicarbonate and hydrogen ions as shown in the equation.

$H_2CO_3 <> H_2O + CO_2 <> H^+ + HCO_3^-$

INDICATION
Sodium Bicarbonate 8.4% w/v Injection is indicated in the treatment of metabolic acidosis and renal calculi caused by uric acid, renal failure, diabetic coma, or following cardiac arrest.

RECOMMENDED DOSAGE
Note: Sodium Bicarbonate 8.4% w/v Injection is equivalent to 1mEq/mL (1 mmol/mL).

Usual adult/peadiatric dose:
I) Systemic alkaliser in cardiac arrest
IV initially 1mEq/kg bodyweight; 0.5mEq/kg of body weight may be repeated every ten minutes of continued arrest.

In less urgent forms of metabolic acidosis IV infusion, 2 to 5mEq/kg of body weight, administered over a period of four to eight hours.

II) Urinary alkaliser
IV infusion 2 to 5mEq/kg of body weight and administered over a period of four to eight hours.

ROUTE OF ADMINISTRATION
Parenteral

CONTRAINDICATIONS
Administration of Sodium Bicarbonate 8.4% w/v Injection is contraindicated in conditions such as alkalosis metabolic or respiratory alkalosis, chloride loss due to vomiting or continuous gastrointestinal suction and hypocalcaemia.

Not to be administered to patients with hypochlorhydria, hypertension, hypoventilation, chloride depletion or hyperosmolar states such as anuria or oliguria, edematous sodium retaining conditions such as hepatic cirrhosis, congestive heart failure and toxemia of pregnancy.

Administration of sodium bicarbonate is contraindicated in patients taking diuretics known to produce hypochloremic alkalosis.

WARNINGS AND PRECAUTIONS
Sodium Bicarbonate 8.4% w/v Injection solution may be administered intravenously or following dilution to isotonicity (1.5%) subcutaneously. For subcutaneous administration, an isotonic solution
(1.5%) of Sodium Bicarbonate may be prepared by diluting 1mL of 8.4% w/v Sodium Bicarbonate with 4.6mL of sterile water for injection.

Adequate alveolar ventilation must be ensured following Sodium Bicarbonate administration during cardiac arrest, to allow for the continued excretion of the carbon dioxide released. This is important for the control of arterial pH.

Overtreatment with bicarbonate must be avoided. Frequent monitoring of serum electrolytes and acid-base status is essential.

Sodium bicarbonate should be administered with extreme caution to patients with oedema, aldosteronism, potassium depletion or respiratory acidosis.

INTERACTION WITH OTHER MEDICAMENTS
Caution should be used when administering sodium ions to patients receiving corticosteroids or corticotropin.

Urinary alkalisation will increase renal clearance of tetracyclines, especially doxycycline. It will increase the half-lives and duration of action of basic drugs such as quinidine, amphetamines, ephedrine and pseudoephedrine.

Concurrent use in patients taking potassium supplements decreases serum potassium concentrations by promoting an intracellular ion shift. Hypochloremic alkalosis may occur if used in conjunction with potassium – depleting diuretics such as bumetanide, etacrynic acid, furosemide and thiazides.

INCOMPATIBILITIES
Precipitant haze will occur when added to parenteral solutions containing calcium.

PREGNANCY AND LACTATION
Pregnancy
Use with caution, under the supervision of a physician.
Safe use during pregnancy has not been established.

Lactation
Patients requiring intravenous infusions of sodium bicarbonate are unlikely to be in a fit condition to breast-feed.

SIDE EFFECTS
- Common side effects following the administration of parenteral Sodium Bicarbonate are belching of swelling of stomach due to the release of carbon dioxide, stomach cramps and unusual increase in thirst.
- Undiluted sodium bicarbonate injection is hypertonic. Tissue necrosis, ulceration or sloughing has been reported following extravasation at the site of injection.

SYMPTOM & TREATMENT OF OVERDOSE
Symptoms
Toxic doses cause metabolic alkalosis which is manifested as irregular heartbeat, muscle cramps, unusual tiredness, swelling of feet, mood or mental changes, muscle pain, nervousness, restlessness, and unpleasant taste in mouth.

Compensatory hyperventilation, paradoxical acidosis in the cerebrospinal fluid, severe hypokalemia, volume overload, pulmonary oedema, shortness of breath, muscle weakness (associated with potassium depletion). Muscle hypertonicity, twitching, hyperirritability and tetany may develop especially in hypocalcaemic patients. Seizures may be exacerbated or precipitated in epileptic patients.

Excessive doses of sodium salts may also lead to sodium overloading and
hyperosmolality.

Treatment
Discontinue the administration of sodium bicarbonate. For treatment of overdosage, if alkalosis occurs, symptoms may be controlled by the rebreathing of expired air from a paper bag or mask. If severe alkalosis occurs, parenteral injection of Calcium Gluconate should be administered. Treatment of metabolic alkalosis associated with bicarbonate consists mainly of correction of fluid levels and electrolyte balance as well as any hypernatraemia associated with excessive sodium intake. In severe alkalosis, an intravenous infusion of 2.14% ammonium chloride is recommended, except in patients with pre- existing hepatic disease.

STORAGE CONDITION
Store below 30°C.
Caution: Do not use if solution contains growth, particles, turbidity or if there is any change of appearance.

Solutions of Sodium Bicarbonate should not be boiled or heated. When heated, it may decompose and be converted to the carbonate.

SHELF LIFE
3 years after date of manufacture.

DOSAGE FORMS AND PACKAGING AVAILABLE
- 10 x 10mL ampoules (Clear)

PRODUCT REGISTRATION HOLDER /MANUFACTURER
Pharmaniaga LifeScience Sdn. Bhd. (198201002939)
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