

# Sodium Bicarbonate

## Sodium bicarbonate 8.4 % w/v injection BP

### Presentation

Sodium Bicarbonate 8.4 % in water for injections is a sterile, pyrogen and preservative free preparation supplying 1 mmol of sodium and 1 mmol of bicarbonate ions per mL. The pH of the solution is approximately 7.8.

### Uses

#### *Actions*

Sodium bicarbonate is a systemic alkalinising agent which, when given intravenously will increase plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis.

#### *Pharmacokinetics*

Sodium bicarbonate dissociates in water to provide sodium ( $\text{Na}^+$ ) and bicarbonate ( $\text{HCO}_3^-$ ) ions. Sodium is the principal cation of the extracellular fluid. Bicarbonate is a normal constituent of body fluids and the normal plasma level ranges from 24 to 31 mmol/L. Plasma concentration is regulated by the kidney. The bicarbonate anion, at the correct concentration of hydrogen ion ( $\text{H}^+$ ) may be converted to carbonic acid ( $\text{H}_2\text{CO}_3$ ), then to its volatile form, carbon dioxide ( $\text{CO}_2$ ) which is excreted by the lung. Normally, a ratio of 1:20 (carbonic acid: bicarbonate) is present in the extracellular fluid. In a healthy adult with normal kidney function, practically all the glomerular filtered bicarbonate ion is reabsorbed and less than 1% is excreted in the urine.

#### *Indications*

Sodium bicarbonate is used as an alkalinising agent in the treatment of metabolic acidosis which may occur in many conditions including diabetes, starvation, hepatitis, cardiac arrest, shock, severe dehydration, renal insufficiency, severe diarrhoea, Addison's disease or administration of acidifying salts (e.g. excessive sodium chloride, calcium chloride, ammonium chloride).

Sodium bicarbonate is also used to increase urinary pH in order to increase the solubility of certain weak acids (e.g. cystine, sulphonamides, uric acid) and in the treatment of certain intoxications (e.g. methanol, phenobarbitone, salicylates) to decrease renal absorption of the drug or to correct acidosis.

### Dosage and Administration

Sodium Bicarbonate Injection is administered by the intravenous route. Product is for single use in one patient on one occasion only.

Dosage of sodium bicarbonate injection is determined by the severity of the acidosis, appropriate laboratory determinations, and the patient's age, weight and clinical condition.

In cardiac arrest, an initial dose of 1 mEq/kg may be given, followed by 0.5 mEq/kg at ten minute intervals.

In infants (up to 2 years of age) a 4.2% solution is recommended for i.v. administration at a dose not to exceed 8 mmol/kg/day. Slow administration rates and a 4.2% solution are recommended in neonates to minimise the possibility of producing hypernatraemia, decreasing cerebrospinal fluid pressure and inducing intracranial haemorrhage.

In less urgent forms of metabolic acidosis, sodium bicarbonate injection may be added to other i.v. fluids (*see Incompatibilities*). The amount of bicarbonate to be given to older children and adults over a 4 to 8 hour period is approximately 2 to 5 mmol/kg of bodyweight, depending upon the severity of the acidosis as judged by the lowering of the total CO<sub>2</sub> content, blood pH and clinical condition of the patient. Bicarbonate therapy should always be planned in a stepwise fashion since the degree of response from a given dose is not precisely predictable.

In general, it is unwise to attempt full correction of a low total CO<sub>2</sub> content during the first 24 hours of therapy, since this may be accompanied by an unrecognised alkalosis because of a delay in the readjustment of ventilation to normal.

## Contraindications

Sodium bicarbonate is contraindicated in patients with renal failure, respiratory or metabolic alkalosis, hypoventilation, hypernatraemia, hypertension, oedema, congestive heart failure, eclampsia, aldosteronism, a history of urinary calculi and consistent potassium depletion or hypocalcaemia.

It is also generally contraindicated in patients with excessive chloride loss from vomiting or continuous GI suctioning, and in patients at risk of developing diuretic induced hypochloraemic alkalosis.

## Warnings and Precautions

Laboratory determination of the patient's acid base status is recommended before and during treatment to minimise the possibility of overdose and resultant metabolic alkalosis.

Accidental extravascular injection of hypertonic solutions may cause vascular irritation or sloughing.

Rapid injection (10 mL/min) of hypertonic sodium bicarbonate injection solutions into neonates and children under 2 years of age may produce hypernatraemia, a decrease in cerebrospinal fluid 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. It should also be noted that administration of sodium bicarbonate 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.

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

Sodium bicarbonate should be used with caution in patients with cirrhosis.

Solutions containing sodium may cause fluid overload when given in excess. Excessively elevated plasma sodium concentrations may cause dehydration of the brain, resulting in somnolence and confusion, which may progress to convulsions, coma, respiratory failure and ultimately death.

The use of scalp veins should be avoided.

Do not use the injection if it contains precipitate. Do not use unless the solution is clear and the container and seal are intact. Discard any unused portion.

### **Use in Pregnancy and Lactation**

The use of sodium bicarbonate injection, as with any drug, in pregnant or lactating women should only be undertaken if the expected benefit outweighs the possible risk to the mother and foetus or child.

Animal reproduction studies have not been conducted with Sodium Bicarbonate.

### **Adverse Effects**

Alkalosis and/or hypokalaemia may ensue as a result of prolonged use or over correction of the bicarbonate deficit.

Hypernatraemia has been reported with sodium bicarbonate use, especially in patients with renal disease. Hyperosmolality has also been associated with sodium bicarbonate use.

Accidental extravasation of i.v. hypertonic solutions of sodium bicarbonate have been reported to cause chemical cellulitis, with tissue necrosis, tissue calcification, ulceration or sloughing at the site of infiltration. Prompt elevation of the part, warmth and local injection of lignocaine or hyaluronidase are recommended to prevent sloughing of extravasated i.v. infusions.

Hyperirritability or tetany may occur, caused by rapid shifts of free ionised calcium or due to serum protein alterations arising from the pH changes.

Cerebral oedema has occurred with sodium bicarbonate use and a possibility of intracranial haemorrhage exists.

Hypercapnia has occurred in patients receiving sodium bicarbonate and with fixed ventilation.

### **Interactions**

Solutions containing sodium ions should be used with great care, if at all, in patients receiving corticosteroids or corticotropin.

Urinary alkalisation will increase the renal clearance of tetracyclines, especially doxycycline, but 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 bumetanide, ethacrynic acid, frusemide and thiazides. Concurrent use in patients taking potassium supplements may reduce serum potassium concentration by promoting an intracellular ion shift.

The following drugs may have enhanced or prolonged effects due to concomitant administration with sodium bicarbonate: flecainide.

The following drugs may have decreased effectiveness due to concomitant administration with sodium bicarbonate: aspirin and other salicylates, barbiturates, lithium.

The following drugs have been reported to be susceptible to inactivation on mixing with sodium bicarbonate solution: adrenaline HCl, benzylpenicillin potassium, carmustine, glycopyrronium bromide, isoprenaline HCl and suxamethonium chloride.

### **Effects on Laboratory Tests**

False positive Labstix® for urine protein may result due to the high urinary alkalinity produced by sodium bicarbonate.

## **Overdosage**

**Symptoms:** Metabolic alkalosis, which may be, accompanied compensatory hyperventilation, paradoxical acidosis of the cerebrospinal fluid, severe hypokalaemia, hyperirritability or tetany.

**Treatment:** The bicarbonate should be stopped and the patient managed according to the degree of alkalosis present. To control the symptoms of alkalosis the patient should rebreathe expired air. Sodium chloride injection 0.9% may be given intravenously, potassium chloride also may be indicated if there is hypokalaemia.

Calcium gluconate may be used to control hyperirritability and tetany which can occur in severe alkalosis. Ammonium chloride may also be indicated as an acidifying agent in severe cases.

## **Pharmaceutical Precautions**

This product is for single use in one patient on one occasion only. Discard any unused portion.

### **Storage**

Store at or below 30 °C

## **Incompatibilities**

Sodium bicarbonate is incompatible with certain substances in solution and specialised literature should be consulted.

Sodium bicarbonate is incompatible with acids, acidic salts and many alkaloidal salts. Sodium bicarbonate solutions should not be mixed with calcium or magnesium salts, cisplatin, dobutamine hydrochloride, labetalol hydrochloride or oxytetracycline hydrochloride as this may result in formation of insoluble precipitates. Sodium bicarbonate is also incompatible with, corticotrophin, hydromorphone hydrochloride, insulin, magnesium sulphate, methicillin sodium, narcotic salts, noradrenaline acid tartrate, pentobarbitone sodium, procaine hydrochloride, promazine hydrochloride (in glucose injection), streptomycin sulphate, tetracycline hydrochloride, thiopentone sodium, vancomycin hydrochloride, lactated Ringer's injection, sodium lactate injection or Ringer's injection.

The following drugs have been reported as susceptible to inactivation when mixed with sodium bicarbonate solution: adrenaline hydrochloride, benzylpenicillin, carmustine, glycopyrronium bromide, isoprenaline hydrochloride, potassium and suxamethonium chloride.

## **Medicine Classification**

General sale medicine

## **Package Quantities**

Pack of 10 vials.

## **Further Information**

In addition to 84 mg/mL sodium bicarbonate, the injection contains disodium edetate and water for injection. Does not contain preservatives.

## **Name and Address**

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## **Date of Preparation**

21 February 2007