



Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany



8.4% w/v Sodium Bicarbonate Intravenous Infusion

Composition

1000 ml of solution contain
Sodium bicarbonate

84.0 g

Electrolyte concentrations:

Na⁺ 1000 mmol/l
HCO₃⁻ 1000 mmol/l

Excipients:

Disodium edetate
Water for injections

Pharmaceutical form

Solution for infusion
A clear, colourless aqueous solution

Theoretical osmolarity 2000 mOsm/l
pH 7.0 – 8.5

Pharmacodynamic properties

Pharmacotherapeutic group: IV solutions, solutions affecting the electrolyte balance, electrolytes
ATC-Code: B05B B01

Mechanism of action

The pharmacological properties of sodium bicarbonate result from its physiological role in the HCO₃⁻/CO₂ buffer system.

Pharmacodynamic effects

Exogenously administered sodium bicarbonate rapidly absorbs hydrogen ions from the extracellular space and thus leads to a rise of the pH in the organism.

Secondary pharmacodynamic effects

By this buffering process carbon dioxide is produced which is subsequently eliminated via the lungs. Therefore lung function should be unimpaired. Otherwise a marked rise of the pCO₂ will cause an aggravation of intracellular acidosis.

The raise of the blood pH also affects the electrolyte balance. The cellular potassium uptake is increased, so hypokalaemia may be provoked or an existing hypokalaemia may be aggravated. The binding of calcium to plasma proteins is increased, so hypocalcaemia may be provoked or an existing hypocalcaemia may be aggravated.

Pharmacokinetic properties

Distribution

Bicarbonate readily passes across the placental barrier but it passes only slowly across the blood-brain barrier.

Elimination

In the kidneys, bicarbonate is filtered in the glomeruli and the major portion of it is re-absorbed in the tubules. When plasma bicarbonate concentrations rise to above 24 mmol/l, bicarbonate is excreted by the kidneys. Renal bicarbonate re-absorption is reduced under therapy with diuretics of the thiazide group or those acting on the loop of HENLE.

Indications

- Correction of metabolic acidosis
- Urine alkalinisation:
 - in the case of intoxication with weak organic acids, e. g. barbiturates or acetylsalicylic acid
 - in order to improve the solubility of drug substances that are poorly soluble in neutral or acid medium, e. g. methotrexate, sulphonamides
 - in the case of haemolysis.

Dosage

Correction of metabolic acidosis

Correction of metabolic acidosis should not be effected too rapidly. It is advisable to start administering only half of the calculated dose and adjust further doses according to the actual results of blood gas analysis. The dose depends on the degree of the disorder of the acid-base status. According to the blood gas values the amount to be administered is calculated applying the following formula:

mmol sodium bicarbonate = base deficit × kg body weight × 0.2

(The factor 0.2 corresponds to the proportion of the extracellular fluid in relation to total body weight.)

Example:

If in a patient of 70 kg body weight the base deficit is 5 mmol/l, then 5 × 70 × 0.2 = 70 mmol of sodium bicarbonate (△ 70 ml of Sodium Bicarbonate 8.4% w/v) are to be given.

Maximum daily dose:

According to the correction requirements.

Maximum infusion rate:

Up to 1.5 mmol of sodium bicarbonate per kg body weight per hour

Paediatric population

The dosage has to be adjusted individually. The first dose can be up to 1 mmol/kg body weight, administered by slow intravenous infusion.

In infants (including newborn infants) and toddlers, the daily dose should not exceed 5 mmol per kg body weight per day, administered by slow intravenous infusion. 4.2% w/v (or less concentrated) sodium bicarbonate solutions should be preferred (see also section "Special warnings and precautions for use").

Urine alkalinisation

For urine alkalinisation the dose is adjusted according to the desired pH of the urine and administration should be accompanied by monitoring of the acid-base balance, the water balance and the electrolyte balance. Care should be taken not to exceed the maximum infusion rate stated above. In haemodynamically stable adults and children urine alkalinisation may be achieved with a bolus of 1-2 mmol sodium bicarbonate per kg body weight, followed by an infusion of 132 mmol sodium bicarbonate in 1 litre of glucose 5% in water, with a flow rate of 1.5-2 times the maintenance fluid rate. Urine pH should not exceed 8.5.



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Method of administration

- Intravenous use.
- For central venous infusion only.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed
- Respiratory or metabolic alkalosis
- Hypoventilation
- Hypernatraemia
- Hypokalaemia
- Excessive chloride loss

Special warnings and precautions for use

General

Sodium Bicarbonate should only be administered with particular caution in presence of the following conditions:

- respiratory acidosis
- hypocalcaemia
- increased serum osmolarity
- further in all situations where sodium intake must be restricted, like cardiac insufficiency, oedema, hypertension, eclampsia, severe kidney insufficiency.

When respiratory acidosis is concomitant with metabolic acidosis, both pulmonary ventilation and perfusion must be adequately supported to ensure adequate elimination of excess CO₂.

Administration of Sodium Bicarbonate may lead to sodium and fluid overload.

Accidental paravenous administration may lead to tissue necrosis.

Patient monitoring should include regular checks of the acid-base balance, the serum electrolyte concentrations and the water balance.

Correction of the acid-base status is always associated with shifts of the electrolyte balance. In particular, the potassium balance is affected. Alkalinisation or correction of acidosis promote the potassium influx into cells and may therefore lead to hypokalaemia.

Potassium or calcium deficiencies should be corrected before beginning of the alkalinising therapy.

The effects of bicarbonate on organ function, complication rates and survival in diabetic ketoacidosis, cardiac arrest and lactic acidosis have not been investigated sufficiently. Caution is advised when using sodium bicarbonate in these conditions.

Paediatric population

Newborn infants, infants and toddlers: Rapid infusion (10 ml/min) of hypertonic sodium bicarbonate solutions may produce hypernatraemia, a decrease in cerebrospinal fluid pressure and (in preterm infants) possible intracranial haemorrhage. Do not administer > 5 mmol per kg body weight per day (see also section "Dosage").

Interactions with other medicinal products and other forms of interaction

Urine alkalinisation by sodium bicarbonate accelerates the elimination of acidic drug substances, e.g. acetylsalicylic acid, and delays the elimination of basic drug substances.

Sodium bicarbonate may interact with gluco- and mineralocorticoids, androgens and diuretics increasing the potassium excretion.

Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of sodium bicarbonate in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Sodium bicarbonate should not be used during pregnancy unless the clinical condition of the woman requires treatment with sodium bicarbonate. Bicarbonate readily crosses the placental barrier. Caution should be exercised in toxemia of pregnancy due to the high sodium level of the medicinal product (see section "Special warnings and precautions for use").

Breast-feeding

It is unknown whether sodium bicarbonate/metabolites are excreted in human milk. During breast-feeding the solution should only be given if the benefits clearly outweigh the risks.

Fertility

No data available.

Effects on ability to drive and use machines

Sodium Bicarbonate has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Undesirable effects are listed according to their frequencies as follows:

Very common (≥ 1/10)

Common (≥ 1/100 to < 1/10)

Uncommon (≥ 1/1,000 to < 1/100)

Rare (≥ 1/10,000 to < 1/1,000)

Very rare (< 1/10,000)

Not known (frequency cannot be estimated from the available data)

Metabolism and nutrition disorders

Not known: Hypernatraemia, serum hyperosmolarity

Overdose

Symptoms

Overdose may lead to alkalosis, hypernatraemia, serum hyperosmolarity or hyperhydration. When an acidosis is corrected too rapidly, especially in the presence of ventilatory disorders, the increased liberation of carbon dioxide may transiently aggravate cerebral acidosis.

Treatment

Therapy of alkalosis, depending on its severity: Infusion of physiological saline, substitution of potassium; in marked alkalosis infusion of arginine hydrochloride or hydrochloric acid. In general the patient should be treated symptomatically and electrolytes and acid-base balance should be monitored.

Incompatibilities

Due to their alkaline pH, sodium bicarbonate solutions are incompatible with most medicinal products. In particular, they must not be administered simultaneously with solutions containing calcium, magnesium or phosphate because of the possibility of precipitation.

Expiry date

The product must not be used beyond the expiry date stated on the labelling.

Special precautions for storage

To avoid formation of crystals, do not refrigerate or freeze.

Do not store above 25 °C.

Presentation

100 ml, 250 ml, 500 ml

Not all pack sizes may be marketed.

Special precautions for disposal and other handling

No special requirements for disposal.

Containers are for single use only. Discard container and any unused content after use.

Only to be used if the solution is clear and colourless and if the bottle and its closure are undamaged.

This medicinal product is an almost saturated solution and should therefore not be stored below normal room temperature. Crystals which may possibly have developed during storage can be dissolved by simply warming the bottle. As an additional safety measure against crystals that might be inadvertently infused with the solution, it is recommended to use an infusion set fitted with an integral fluid filter.

The solution should be administered immediately after connecting the container to the giving set.

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