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Directions for Use

B. Braun Melsungen AG · D-34209 Melsungen

8.4% w/v Sodium Bicarbonate Intravenous Infusion

Composition

1000 ml of solution contain:

Sodium bicarbonate	84.0 g

Excipients:

Disodium edetate dihydrate, water for Injections

Electrolyte concentrations:

Sodium	1000 mmol/l
Bicarbonate	1000 mmol/l
Theoretical osmolarity	2000 mOsm/l
Titration alkalinity (to pH 7.4)	approx. 80 mmol/l
pH	7.0 - 8.5

Pharmaceutical form

Solution for infusion

Pharmaco-therapeutic group

Solution for electrolyte substitution

Indications

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

Contraindications

8.4 % w/v Sodium Bicarbonate Intravenous Infusion must not be administered to patients with

- respiratory and metabolic alkalosis,
- hypernatraemia,
- hypokalaemia.

Special warnings and precautions for use

8.4 % w/v Sodium Bicarbonate Intravenous Infusion should only be administered with particular caution in presence of the following conditions:

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

Administration of 8.4 % w/v Sodium Bicarbonate Intravenous Infusion may lead to sodium and fluid overload.

It must be made absolutely sure that the solution is infused intravenously; accidental intra-arterial infusion may cause shock or loss of an extremity.

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. Alkalisation 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 alkalising therapy.

Interactions

Urine alkalisation by sodium bicarbonate accelerates the elimination of acid 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.

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

Dosage

For correction of metabolic acidosis 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 according to the following formula:

ml of 1 M (8.4 % w/v) sodium bicarbonate solution
= base deficit x kg b.w. x 0.3

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(The factor 0.3 corresponds to the proportion of the extracellular fluid in relation to total body fluid).

Example:
If in a patient of 70 kg b.w. the base deficit is 5 mmol/l, then
5 x 70 x 0,3 = 105 ml of 8.4 % w/v Sodium Bicarbonate Intravenous Infusion are to be given.
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.
For urine alkalisation the dose is adjusted according to the desired pH of the urine and administration should be accompanied by monitoring of the acid-base balance and the water balance. Care should be taken not to exceed the maximum infusion rate stated below.

Maximum daily dose:
According to the correction requirements.

Flow rate:
Up to 1.5 mmol of sodium bicarbonate/kg b.w./h, corresponding to 1.5 ml of solution/kg b.w./h.

Method of administration
Intravenous use.
The solution must be infused into a central vein.

Overdose

Symptoms
If infused undiluted or too rapidly into peripheral veins, 8.4 % w/v Sodium Bicarbonate Intravenous Infusion may cause vein irritation and consecutively phlebitis or thrombosis on account of its alkalinity and its high osmolarity.
Overdose may lead to alkalosis, hypernatraemia, and serum hyperosmolarity. When an acidosis is corrected too rapidly, esp. in cases of concomitant respiratory disorders, the increased liberation of carbon dioxide may transiently aggravate cerebral acidosis.

Emergency treatment, antidotes
Therapy of alkalosis, depending on its severity: Infusion of physiological saline, substitution of potassium; for correction of marked alkalosis infusion of arginine hydrochloride or hydrochloric acid.

Undesirable effects
Administration of 8.4% w/v Sodium Bicarbonate Intravenous Infusion may lead to hypernatraemia, and serum hyperosmolarity.
Paravenous administration may lead to tissue necrosis.

Note:
Patients are advised to inform their doctor or pharmacist of any adverse effect they experience in connection with the administration of this drug.

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

Instructions for storage / use / handling
Only to be used if solution is clear and container undamaged.
The solution is supplied in single-dose containers. Unused portions of the solution must be discarded.
The solution is almost saturated. It should not be stored below room temperature. Possible crystallisation can be reversed by gently warming up the solution.

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