201/12260746/0421

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

8.4% w/v Sodium Bicarbonate Intravenous Infusion BP

Composition
100 ml solution contain:

Active ingredient:
Sodium Bicarbonate 8.4 g

Excipients:
Disodium Edetate · 2 H_2O water for Injections

Electrolyte concentrations:
Sodium 1000 mmol/l
Bicarbonate 1000 mmol/l

Osmolarity: 2000 mOsm/l

Pharmaceutical form
Solution for injection/infusion

Pharmaco-therapeutic group
Electrolyte-solution for correction of acid-base imbalances (acidoses).

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

Contraindications
Respiratory and metabolic alkalosis,
Hypernatremia,
Hypokalemia.

Precautions for use
Patient monitoring should include regular checks of the acid-base balance, the serum electrolyte concentrations and the water balance.
Hypokalemia or hypocalcemia should be corrected before beginning of the alkalinising therapy.

Interactions
Urine alkalinisation by sodium bicarbonate increases the elimination rates of acid drug substances, e.g. acetylsalicylic acid, and decreases the elimination rates 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.

Special warnings
Sodium Bicarbonate Intravenous Infusion BP should not be administered in the following situations unless it has been established that its expected benefits clearly outweigh potential risks:
- Hypoventilation,
- Hypocalcemia,
- Increased serum osmolarity,
- Further in all situations where sodium intake must be restricted like cardiac insufficiency, oedema, hypertension, eclampsia, severe kidney insufficiency.

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

B|BRAUN

Schwarz
148x210 mm
201/12260746/0421
Lätus: 3760
Singapur
Font size 8,5

Approval for Printing
B|BRAUN Melsungen AG

Approved for Printing ☐
Approved for Printing when corrected ☐
New draft required ☐

LRA: Date Signature
Name in capital letters

LMS: Date Signature
Name in capital letters

201/12260746/0421

Dosage
The quantity of Sodium Bicarbonate Intravenous Infusion BP to be infused is determined by the blood gas values and is calculated according to the following formulae:
ml of 8.4%w/v Sodium Bicarbonate Intravenous Infusion BP
= negative base excess x kg b.w. x 0.3
(The factor 0.3 corresponds to the proportion of the extracellular fluid in relation to total body fluid).
The maximum daily dose is determined according to the correction requirements.

Correction of metabolic acidosis should not be affected 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.
Blind buffer therapy is not advisable. It should only be performed in life-threatening situations.

Flow rate
Up to 1.5 mmol of sodium bicarbonate per kg body weight per hour, corresponding to 1.5 ml of 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP/kg bw/h.

Route of administration
Strictly intravenously! 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP has an osmolarity of about 2000 mOsm/l and, when infused undiluted, it should be administered via central venous catheter, preferably inserted into the vena cava.

Overdose
Overdose may lead to alkalosis, hypernatremia, 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.
Therapy of alkalosis, depending on its physiological saline, substitution of potassium; in marked alkalosis infusion of arginine hydrochloride or hydrochloric acid.

Undesirable effects
Administration of Sodium Bicarbonate Injection may lead to hypernatremia, and serum hyperosmolarity.
Paravenous administration may lead to tissue necrosis.

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

Storage
8.4% w/v Sodium Bicarbonate Intravenous Infusion BP: Do not store above 30°C and do not refrigerate or freeze. Possible crystallisation can be reversed by gently warming up the solution. As an additional protective measure against crystals inadvertently infused with the solution, it is recommended to use an administration set fitted with an integral fluid filter.

Presentation
Glass bottle of 100 ml, 250 ml

B|BRAUN

B. Braun Melsungen AG
34209 Melsungen
Germany

Schwarz
148x210 mm
201/12260746/0421
Lätus: 3760
Singapur
Font size 8,5