51/12614076/0816

Directions for use
Read carefully!

B. Braun 20% Sodium Chloride Concentrate B.P.

Composition
100 ml of solution contain

Active ingredients:
Sodium Chloride 20.0 g

Excipients:
Water for Injections

Theoretical Osmolarity 6800 mOsm/l

1 ml contains 3.4 mmol of sodium and 3.4 mmol of chloride

Pharmaceutical form
Concentrate for infusion

Pharmaco-therapeutic group
Solution for electrolyte substitution

Indications
- Hyponatraemia
- Hypochloraemia
- Hypotonic hyperhydration

Contraindications
B. Braun 20% Sodium Chloride Concentrate B.P. must not be used in cases of
- Hypernatraemia
- Hyperchloraemia

B. Braun 20% Sodium Chloride Concentrate B.P. should only be administered with caution in cases of
- Hypokalaemia,
- Disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalised oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency,
- Therapy with corticosteroids or with ACTH,
- Metabolic acidosis.

Precautions for use

To be diluted before use.

Clinical monitoring should include checks of the serum electrolytes, the water balance, and the acid-base balance.

Interactions
During therapy with corticosteroids or ACTH there may be an increased retention of sodium and chloride.

Incompatibility can arise upon mixing with other medicaments. The attending doctor will decide on the use of mixed infusions.

Dosage
The dose is adjusted according to the analytical values of the serum ionogram and should also be adjusted according to the analytical values of the acid-base status.

The sodium deficit is calculated by the formula:

Sodium deficit (mmol) = $(Na^+_{required} - Na^+_{actual})$ x kg b.w. x 0.2
(The extracellular volume is calculated as body weight x 0.2)

Maximum daily dose
The maximum daily dose depends on the actual need of electrolytes. As a rule, the daily dose for adults is 3 - 6 mmol/kg b.w., for children 3 - 5 mmol/kg b.w.

Maximum infusion rate
The maximum infusion rate depends on the prevailing clinical situation.

Method of administration
Intravenous use, only diluted by addition to a suitable infusion solution.

In general, the calculated amount of sodium chloride is added to 250 ml of fluid. In cases of fluid deficit larger volumes of vehicle solution may be used. For infusion into peripheral veins, the solution must be diluted so as not to exceed an osmolarity of 800 mOsm/l.

Care should be taken to add the sodium chloride concentrate to the infusion solution under strictly aseptic conditions immediately before setting up the infusion. After mixing the infusion bottle should be gently shaken.

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Dokument = 148 x 210 mm
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B. Braun 20% Sodium Chloride
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Overdose

Symptoms
Too rapid infusion of hypertonic solutions may cause acute volume overload. Overdose may cause hypernatraemia and hyperchloraemia, serum hyperosmolarity, and metabolic acidosis.

Emergency treatment, antidotes
Stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.

Undesirable effects
Administration of B. Braun 20% Sodium Chloride Concentrate B.P. may lead to hypernatraemia and hyperchloraemia.

Too rapid infusion of solutions with high sodium concentration may cause acute volume overload, osmotic diuresis and diarrhoea, further hypernatraemia and hyperchloraemia.

Infusion of solutions with high sodium concentration into peripheral veins may cause vein irritation or even phlebitis.

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

Usage during pregnancy
No adverse reaction has been reported. However, these injections should be given to a pregnant woman only if clearly needed.

Storage
The product should not be stored above the temperature stated on the label.

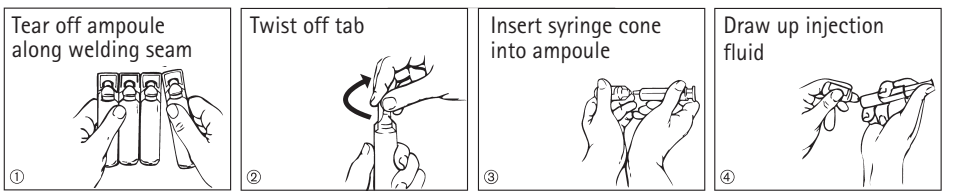
Shelf life
The product must not be used beyond the expiry date stated on the label.

Presentation
In plastic ampoules "Mini-Plasco®" and "Mini-Plasco® Connect" of 10 ml, 20 ml in box of 20's.

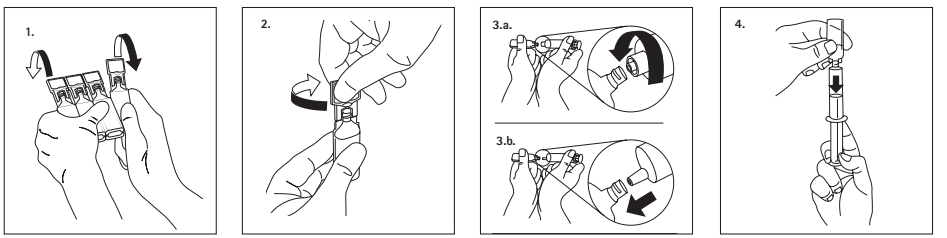
Instructions for use / handling
The product is supplied in single-dose containers. Discard unused contents.

Only to be used if solution is clear and container undamaged.

Mini-Plasco® Handling



Mini-Plasco® Connect Handling



Product registration holder and manufactured by:
B. Braun Medical Industries Sdn. Bhd.
11900 Bayan Lepas, Penang, Malaysia.

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