SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000,0 mL of solution contains 9,0 g Sodium Chloride.

Millimoles per 1000,0 mL: Sodium 154

Chloride 154

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection

Clear, colourless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN injection is used in a wide range of clinical situations for:

- Prevention of fluid and electrolyte deficits or imbalances;
- Corrections of fluid and electrolyte deficits or imbalances.

4.2. Posology and method of administration

Posology

Dosage will be determined by the attending healthcare professional, which will depend on the extent of electrolyte loss.

When physiological conditions are re-established, dosage must be reduced.

Method of administration

Administered intravenously, using sterile equipment.

4.3. Contraindications

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN injection is contraindicated in:

- Hypersensitivity to any sodium chloride or excipients (see section 6.1).

4.4. Special warnings and precautions for use

- Use only if solution is clear and free from visible particles.
- Discontinue infusion if any adverse reactions occurs.
- Check for adequate renal function and clinical signs of hydration.
- Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function or pre-eclampsia.
- Care should also be taken when administering sodium chloride intravenously to very young or elderly patients.
- In order prevent osmotic demyelination syndrome from developing, serum sodium concentrations should not exceed 9 mmol/L/day. As a general recommendation, a rate of correction of 4 to 6 mmol/L/day is considered appropriate in the majority of cases, depending on the patient's conditions and associated risk factors.
- Clinical monitoring should include checks of the serum ionogram, water balance and the acid-base balance.
- If the rapid infusion of 0,9 % NaCl is required, the cardiovascular and respiratory status should be monitored closely.

Paediatric population

Premature or newborn babies may develop excess sodium levels due to immature kidney function. Therefore, repeated sodium chloride infusions should only be administered after serum sodium levels have been determined.

4.5. Interaction with other medicines and other forms of interaction

Medicinal products leading to sodium retention

The simultaneous use of sodium-retaining medicinal products (e.g. corticosteroids, non-steroidal anti-inflammatory medicines) can lead to oedema.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of **SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN** in pregnant women. Similarly, animal studies are insufficient with respect to reproductive toxicity.

Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN may therefore be used as stated.

Caution must be exercised, however, in the event of eclampsia (see section 4.4).

Lactation

Sodium chloride is excreted in human milk. Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN may be used during lactation if required.

Fertility

No data are available.

4.7. Effects on ability to drive and use machines

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

- Continued infusion may lead to dilutional hyponatraemia and expanded extracellular volume.
- Convulsions can result from iatrogenically induced hypernatraemias.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '6.04 Adverse Drug Reactions Reporting Form'. Found under SAHPRA's publications: https://www/sahpra.org.za/Publications/Index/8

4.9. Overdose

Symptoms

Excessive administration of **SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN** may cause hypernatraemia, hyperchloraemia, hyperhydration, acute volume overload, oedema, serum hyperosmolality and hyperchloraemic acidosis.

In patients with chronic hyponatraemia, a rapid rise in the serum sodium concentration can lead to osmotic demyelination syndrome (see section 4.4).

The first signs of overdose may be thirst, confusion, sweating, headache, weakness, drowsiness or tachycardia. Hypertension or hypotension, respiratory failure or coma may occur in the event of severe hypernatraemia.

Treatment

Depending on the severity of the symptoms, immediate stopping of the infusion and administration of diuretics whilst constantly monitoring serum electrolytes, and correction of electrolyte and acid-base imbalances.

Dialysis may be required in the event of major overdosage or oliguria or anuria.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A 24 Mineral substitutes, electrolytes

ATC code: B05B B01

Mechanism of action

Sodium is the primary cation in the extracellular space and, together with various anions, regulates the size of the latter. Sodium is one of the major mediators of bioelectric processes within the body.

Chloride is the main osmotically active anion in the extracellular space.

A rise in the serum chloride concentration leads to increased renal bicarbonate excretion.

An acidifying effect is therefore induced through the administration of chloride.

Pharmacodynamic properties

The sodium content and fluid metabolism in the body are closely connected. Each deviation in plasma sodium from the physiological concentration simultaneously affects the body's fluid status.

Independently of serum osmolality, a rise in the sodium content within the body also means a drop in free body water.

An 0,9 % solution of sodium chloride has the same osmolarity as plasma. Administration of this solution leads primarily to filling of the interstitial space, which represents roughly 2/3 of

the whole extracellular space. Only 1/3 of the volume administered remains in the intravasal space. The haemodynamic effect of the solution is therefore only short-lasting.

5.2. Pharmacokinetic properties

Absorption

As the solution is administered as an intravenous infusion, the bioavailability of the solution is 100 %.

Distribution

The body's total sodium content is approximately 80 mmol/kg (5600 mmol), of which 300 mmol can be found in intracellular fluid in a concentration of 2 mmol/L and 2500 mmol of which are bound in bones.

Approximately 2 mol can be found in extracellular fluid in a concentration of 135 - 145 mmol/L (3,1 – 3,3 g/L).

The total chloride content in the body is approximately 33 mmol/kg bodyweight. Serum chloride ranges from 98 to 108 mmol/L.

Biotransformation

Although sodium and chloride are absorbed, distributed and excreted, they are not metabolised in the strict sense.

The kidneys are the main regulators of sodium and fluid balance. Together with hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and with the hypothetical natriuretic hormone, they are chiefly responsible for keeping the volume of the extracellular space constant and for its fluid composition.

Chloride is exchanged for hydrogen carbonate in the tubule system and, in this way, is involved in the regulation of the acid-base balance.

Elimination

Sodium and chloride are excreted via sweat, urine and the gastrointestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for injection.

6.2. Incompatibilities

Additives may be incompatible.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

SODIUM CHLORIDE 0,9 % INFUSION B. BRAUN is packed in:

- 50 mL clear, colourless polyvinylchloride bag enclosed in a heat sealed off-white polyethylene pouch.
- 100 mL clear, colourless polyvinylchloride bag enclosed in a heat sealed off-white polyethylene pouch.
- 200 mL clear, colourless polyvinylchloride bag enclosed in a heat sealed off-white polyethylene pouch.
- 1000 mL clear, colourless polyvinylchloride bag enclosed in a heat sealed off-white polyethylene pouch.

The bags are equipped with an admin port and an additive port. During filling a 9,8 mm stopper (polycarbonate outer shell and a rubber inner shell), will be placed into the admin port.

Not all packs or pack sizes are necessarily marketed.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

The containers are intended for single use only. After administration, the container and any remaining solution are to be discarded.

Do not use if the solution is not clear and colourless and free from visible particles, or if the container and its closure show any visible signs of damage.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

32/24/0128

9. DATE OF FIRST AUTHORISATION

16 February 1999

10. DATE OF REVISION OF TEXT

7 July 2021