1.3.1.1 Professional Information for Human Medicines (Clean)

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

0,9 % w/v SODIUM CHLORIDE B BRAUN (solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of solution contains: Sodium Chloride 0,9 g

Electrolyte concentrations:

Sodium: 154 mmol/L

Chloride: 154 mmol/L

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution

Clear colourless, solution.

Theoretical osmolarity: 308 mOsm/l

Titration acidity: < 0,3 mmo/l

pH: 4,5 - 7,0

4. CLINICAL PARTICULARS :

4.1. Therapeutic indications:

Solvent or diluent for compatible electrolyte concentrates of drugs.

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4.2 Posology and method of administration

Posology:

The quantity to be chosen depends on the desired concentration of the medicament to be dissolved.

Method of administration:

0,9 % w/v SODIUM CHLORIDE B BRAUN can be administered by intravenous or subcutaneous injection.

For the use of 0,9 % w/v SODIUM CHLORIDE B BRAUN as solvent / diluent for compatible electrolyte concentrates or medicaments, the instruction for use relating to the medicament to be added should be observed.

4.3. Contraindications

None

4.4. Special warnings and precautions for use

Caution should be exercised when using 0,9 % w/v SODIUM CHLORIDE B BRAUN in the presence of**:**

- Hypernatremia

– Hyperchloraemia

Patients should be advised to inform their doctor or pharmacist if they notice any adverse reactions in connection with the administration of 0,9 % w/v SODIUM CHLORIDE B BRAUN.

4.5 Interaction with other medicinal products and other forms of interaction

When mixing 0,9 % w/v SODIUM CHLORIDE B BRAUN with other medicaments, possible incompatibilities should be considered.

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4.6 Fertility, pregnancy and lactation

Pregnancy and breastfeeding:

0,9 % w/v SODIUM CHLORIDE B BRAUN can be used as indicated.

No specific risks from the use of this medicinal product during pregnancy and lactation are known.

Fertility:

No data available**.**

4.7 Effects on ability to drive and use machines

0,9 % w/v SODIUM CHLORIDE B BRAUN has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Administration of large amounts of 0,9 % w/v SODIUM CHLORIDE B BRAUN may lead to hypernatraemia or hyperchloraemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report and suspected adverse reactions to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRAs publications: https://www.sahpra.org.za/Publications/index/8.

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4.9 Overdose

An overdose can lead to hypernatraemia, hyperchloraemia, hyperhydration, hyperosmolarity and metabolic acidosis.

Therapy:

Discontinuation of the infusion, administration of diuretics under continuous monitoring of serum electrolytes, correction of electrolyte and acid–base imbalances.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class of the medicine: A.24 Mineral substitutes, electrolytes

Pharmacotherapeutic group: solvents and diluents, including irrigation solutions

ATC code: V07AB

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium and potassium are the major mediators of bioelectric process within the body.

The sodium content and the liquid metabolism of the body are closely coupled.

Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.

An increase in the sodium content of the body also means reduction of the body's free water content, independent of the serum osmolality.

A 0,9 % sodium chloride solution has the same osmolarity as plasma.

Administration of this solution primarily leads to a replenishment of the interstitial space, which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume

remains in the intravascular space. Therefore the haemodynamic effect of the solution is of short duration only.

5.2 Pharmacokinetic properties

The total sodium content of the body is 80 mmol/ kg, of which 97 % is extracellular and 3 % intracellular. The daily turnover is 100 -180 mmol (corresponding to 1,5 – 25 mmol/ kg body weight).

The kidneys are the major regulator of the sodium and water balances. In co-operation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, anti-diuretic hormone) and the extracellular space constant and regulating its fluid composition. Chloride is exchanged for hydrogen carbonate in the tubular system and is thus involved in the regulation of the acid base balance.

5.3. Preclinical safety data

The available data on the safety pharmacology, repeated dose toxicity, toxicity to reproduction, genotoxicity and carcinogenic potential of sodium chloride reveal no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Incompatibilities may occur when this product is mixed with other medicinal products.

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6.3 Shelf life

Unopened:

3 years

After first opening of the container:

0.9 % w/v SODIUM CHLORIDE B BRAUN must be used immediately after first opening.

See also section 6.6.

After the solution has been reconstituted:

From the microbiological point of view, the solution should be used immediately after reconstitution. If the solution is not used immediately, in use storage times and conditions are the responsibility of the user. Under normal circumstances, mixtures with other components should not be stored for longer than 24 hours at 2 °C – 8 °C, unless reconstitution has taken place under controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep in original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

DO NOT USE BEYOND THE EXPIRY DATE STATED ON THE LABELLING

6.5 Nature and contents of container

Carton containing 20, 50 or 100 x 5 ml colourless polyethylene ampoules.

Carton containing 20, 50 or 100 x 10 ml colourless polyethylene or polypropylene ampoules.

Carton containing 20, 50 or 100 x 20 ml colourless polyethylene or polypropylene ampoules.

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Not all packs or pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Only use if the solution is clear and the container and seal are intact.

7 HOLDER OF CERTIFICATE OF REGISTRATION:

B. Braun Medical (Pty) Ltd.

253 Aintree Road

Hoogland Ext. 41

Northriding,

Gauteng

South Africa

2194

Tel :+27 (010) 222 3000

Fax: +27 (010) 222 3133

8. REGISTRATION NUMBER:

A39/24/0312

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION:

06 October 2006

10. DATE OF REVISION OF THE TEXT

11 June 2021