Professional Information For Human Medicine

SCHEDULING STATUS

S1

1. Name of the Medicinal Product

Pour Sodium Chloride 0,9 % B.BRAUN, Solution for irrigation

2. Qualitative and Quantitative Composition

Each1000 mL of solution contains

Active substance: Sodium Chloride 9,0 g

Electrolyte concentrations:

Sodium (Na^+): 154 mmol/L

Chloride (Cl^-): 154 mmol/L

For full list of excipients, see section 6.1.

3. Pharmaceutical Form

Solution for irrigation.

Clear, colourless solution.

4. Clinical Particulars :

4.1. Therapeutic indications

Pour Sodium Chloride 0,9 % B.BRAUN being isotonic, is a useful fluid for sterile irrigation, for example, of the eye or bladder, and general skin or wound cleansing.

4.2 Posology and method of administration

For irrigation only. Not for injection.

As required for irrigation. For single use only. Discard unused portion.

4.3. Contraindications

There are no absolute contraindications to use **Pour Sodium Chloride 0,9 % B.BRAUN.**

4.4. Special warnings and precautions for use

Not to be administered by parenteral injection.

Not for use in electrosurgery.

Solutions for urological irrigation should be used with caution in patients with severe cardiopulmonary oedema, or severe cardiopulmonary or renal dysfunction, since systemic absorption of large amounts of solutions may substantially alter cardiopulmonary or renal function.

Pour Sodium Chloride 0,9 % B.BRAUN should be used with caution in patients with hypertension, heart failure, peripheral or pulmonary oedema, renal impairment, pre-eclampsia, or other conditions associated with sodium retention.

Pour Sodium Chloride 0,9 % B.BRAUN should not be used to induce emesis; this practice is dangerous and deaths from resulting hypernatraemia have been reported.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

The solution is a physiological saline and may be used during pregnancy.

Fertility: No data available

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Systemic absorption of the irrigation solution may cause fluid and/or solute overload resulting in dilution of serum electrolytes, overhydration, congestive conditions, or

pulmonary oedema.

Reporting of suspected adverse reactions:

Reporting suspected adverse reaction after authorisation of the **Pour Sodium Chloride 0,9 % B.BRAUN** is important. It allows continued monitoring of the benefit/risk balance of the **Pour Sodium Chloride 0,9 % B.BRAUN.**

Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section 4.8.

If adverse effects, overhydration, or solute overload occurs with the irrigation solution, it should be discontinued, the patient should be closely evaluated, and appropriate corrective therapy instituted if necessary. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Class of Medicine: A.24 Mineral substitutes, electrolytes.

ATC code: B05CB01

Sodium chloride 0,9 % *m/v* solution exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters, and surgical drainage tubes and for washing, rinsing, or soaking surgical dressings, instruments, and laboratory specimens. It acts as a diluent or vehicle for medicines used for irrigation or other pharmaceutical preparations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Pour Sodium Chloride 0,9 % B.BRAUN is indicated for irrigation only. It acts as a diluent or vehicle for medicines used for irrigation or other pharmaceutical preparations. Additives may be incompatible. Compatibility of the additives with the solution must be assessed before addition. Those additives to be incompatible should not be used.

6.3 Shelf life

-Unopened: 2 years

-After first opening of the container: **Sodium Chloride Infusion 0,9 % B Braun** must be used immediately after first opening.

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

6.5 Nature and contents of contain

1 litre polypropylene container enclosed container with red polyethylene cap.

Not all packs and pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

Do not use unless contents are clear and container is intact.

Do not use if any seal compromise is indicated.

Seal must be complete and intact prior to opening of container.

7 HOLDER OF THE CERTIFICATE OF REGISTRATION:

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8. REGISTRATION NUMBER:

32/24/0563

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

21 January 2000

10. DATE OF REVISION OF THE TEXT

7 July 2021