NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 4.5 mg/ml and Glucose 25 mg/ml Solution for Infusion

COMPOSITION

1000 ml of solution for infusion contain:

Sodium chloride 4.50 g

Glucose 25.00 g (as glucose monohydrate, 27.50 g)

Electrolytes

Sodium 77 mmol/l Chloride 77 mmol/l

Excipient: Water for injection.

THERAPEUTIC INDICATIONS

Hypertonic dehydration, vehicle solution for compatible electrolyte concentrates and medicinal products.

CONTRAINDICATIONS

Hyperhydration, hypotonic dehydration, acute ischemic stroke, head trauma (first 24 hours).

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Not known: (cannot be estimated from the available data)

Metabolism and nutrition disorders:

Not known: Hospital Acquired Hyponatraemia

Neurological disorders:

Not known: Hyponatraemic encephalopathy

Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy.

Adverse reactions may be associated with the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis.

Adverse reactions may be associated with the medications added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects.

WARNINGS

Keep out of the sight and reach of children. For single use only. Discard container and unused contents after use. For single use only. Discard unused contents. Use only if solution is clear and colourless and container and closure are undamaged.

NOTE

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34209 Melsungen, Germany, 07/2018



& Signature Page

Title: 0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion Initiator: Roxana? Tranca

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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