

- Mandatory Text -0.45 % w/v Sodium Intravenous Infusion

B. Braun Melsungen AG Pharma - Regulatory Affairs

Document ID: RA-HC PHARMA-220349

Version: 1.0

Effective Date: 2018-11-12

Page: 1 of 3

NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 4.5 mg/ml B. Braun solution for Infusion

COMPOSITION

Anyone receiving this document in error should immediately notify B. Braun's Legal Department and retum this documen

1000 ml of solution for infusion contain:

Sodium chloride 4.5 g

Theroretical osmolarity: 154 mOsm/l

Electrolyte concentrations:

Sodium 77 mmol/l Chloride 77 mmol/l

Excipient: Water for injection.

THERAPEUTIC INDICATIONS

Hypertonic dehydration and hypochloremic alkalosis, vehicle solution for compatible medicinal products.

CONTRAINDICATIONS

Sodium Chloride 4.5 mg/ml solution for infusion must not be used in cases of hyperhydration, hypotonic dehydration, hypokalemia, hyponatremia.

UNDESIRABLE EFFECTS

Hospital acquired hyponatremia*, hyponatremic encephalopathy*.

*Hospital acquired hyponatremia may cause irreversible brain injury and death due to development of acute hyponatremic encephalopathy.

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 via the national reporting system.

Effective

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Print Date: 2018-11-16 09:36 (CET)



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Page: 2 of 3

WARNINGS

Keep out of the reach of children.

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, 01/2018

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Page: 3 of 3

Title: 0.45 % w/v Sodium 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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