NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 9 mg/ml B. Braun Solution for Infusion

COMPOSITION

1000 ml of solution for infusion contain:

Sodium chloride	9.00 g
Electrolyte concentrations:	
Sodium	154 mmol/l
Chloride	154 mmol/l

Excipient: Water for injection.

THERAPEUTIC INDICATIONS

Fluid and electrolyte substitution in hypochloraemic alkalosis, chloride losses, short-term intravascular volume substitution, hypotonic dehydration or isotonic dehydration, vehicle solution for compatible electrolyte concentrates and medicinal products, externally for wound irrigation and for moistening of wound tamponades and dressings.

CONTRAINDICATIONS

Sodium Chloride 9 mg/ml must not be administered to patients in states of hyperhydration, severe hypernatraemia, severe hyperchloraemia.

UNDESIRABLE EFFECTS

None known if used according to the instructions given.

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.

WARNINGS

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

NOTE

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, 02/2016



Document Control & Signature Page

Title: 0.9 % w/v Sodium Chloride Intravenous Infusion Initiator: Roxana ? Tranca

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

UserName: Pfleging, Petra (pflepede) Title: HC-RA-DE08 Manager Global Regulatory Affairs Pharmaceuticals Date: Thursday, 27 September 2018, 10:40 W. Europe Daylight Time Meaning: Document signed as Author

UserName: Elsing, Andreas (elsiande) Title: HC-ME-DE08C Manager Scientific Affairs Date: Friday, 28 September 2018, 09:20 W. Europe Daylight Time Meaning: Approve Document