

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 98312 B Braun 0.9% Sodium Chloride Intravenous Infusion BP 250 mL Bottle

ARTG entry for Medicine Registered

Sponsor B Braun Australia Pty Ltd

Postal Address PO Box 6221, BAULKHAM HILLS DC, NSW, 2153

Australia

ARTG Start Date 4/11/2004
Product Category Medicine
Status Active

Approval Area Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. B Braun 0.9% Sodium Chloride Intravenous Infusion BP 250 mL Bottle

Product Type Single Medicine Product Effective Date 22/11/2013

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

For intravenous fluid therapy designed to correct deficiencies in hydration, electrolyte and energy levels. May also be used as solvents for intravenously administered drugs where compatibility has been established. May also be used for irrigation of wounds and moistening of wound dressings.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Туре	Material	Life Time	Temperature	Closure	Conditions
Bottle	LDPE	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size Poison Schedule

250mL Not scheduled. Not considered by committee

Components

1 . Medicine Component

Dosage Form Injection, intravenous infusion

Route of Administration Intravenous

Visual Identification Clear, colourless solution, practically free of particles.

Active Ingredients

sodium chloride 9 g/L

Other Ingredients (Excipients)

water for injections

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