

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 235990 SODIUM CHLORIDE INJECTION 0.9% 5 mL ampoule

ARTG entry for Medicine Registered

Sponsor Interpharma Pty Ltd

Postal Address PO Box 115, MANLY, NSW, 1655

Australia

ARTG Start Date 22/12/2015
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 . SODIUM CHLORIDE INJECTION 0.9% 5 mL ampoule

Product Type Single Medicine Product Effective Date 6/10/2023

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

Sodium Chloride Injection BP 0.9% can be used as the vehicle for many parenteral drugs and as an electrolyte replenisher for maintenance or replacement of deficits of extracellular fluid. It can also be used as a sterile irrigation medium.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Туре	Material	Life Time	Temperature	Closure	Conditions
Ampoule	PP	5 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted	Not recorded

flow insert

Pack Size/Poison information

Pack Size Poison Schedule

50 ampoules Not scheduled. Not considered by committee

Components

1 . SODIUM CHLORIDE INJECTION 0.9% 5 mL ampoule

Dosage FormInjection, solutionRoute of AdministrationIntramuscularSubcutaneous

Intravenous
Clear, colourless

Visual Identification
Active Ingredients

sodium chloride 9 mg/mL

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Other	Ingredients ((Exci	pients

water for injections

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