Public Summary

Summary for ARTG Entry: 197200 SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 5 mL ampoule

ARTG entry for	Medicine Registered
Sponsor	Fresenius Kabi Australia Pty Ltd
Postal Address	Level 2, 2 Woodland Way, Mount Kuring-gai, NSW, 2080 Australia
ARTG Start Date	30/04/2013
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 BP 0.9%, sodium chloride, 5 mL ampoule

Product Type Single Medicine Product **Effective Date** 22/02/2022

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

As a 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

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	LDPE	24 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
Carton of 20's	Not scheduled. Not considered by committee

Components

1 . SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 5 mL ampoule

Dosage Form	Injection, solution
Route of Administration	Subcutaneous Intravenous Intramuscular
Visual Identification	Clear and colourless.

Active Ingredients

sodium chloride	**9 mg/mL**

Other Ingredients (Excipients)

hydrochloric acid

sodium hydroxide

water for injections