



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	197199	SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 20 mL ampoule
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Fresenius Kabi Australia Pty Ltd	
<b>Postal Address</b>	Level 2, 2 Woodland Way, Mount Kuring-gai, NSW, 2080 Australia	
<b>ARTG Start Date</b>	30/04/2013	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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, 20 mL ampoule

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/07/2021
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#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
Carton of 20's	Not scheduled. Not considered by committee

#### Components

##### 1 . SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 20 mL ampoule

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

#### Active Ingredients

<b>sodium chloride</b>	<b>9 mg/mL</b>
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**Other Ingredients (Excipients)**

hydrochloric acid  
sodium hydroxide  
water for injections

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