

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	197198	SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 10 mL ampoule				
ARTG entry for	Medicine Registe	ered				
Sponsor	Fresenius Kabi Australia Pty Ltd					
Postal Address	Level 2, 2 Woodl Australia	and Way, Mount Kuring-gai, NSW, 2080				
ARTG Start Date	30/04/2013					
Product Category	Medicine					
Status	Active					
Approval Area	Drug Safety Eval	luation 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 CH	LORIDE INJECT	ION BP 0.9%, so	dium chloride, 10 mL	ampoule				
Product Type	Single Medicine Pr	oduct	Effective Date	14/07/2021				
Permitted Indication	ıs							
No Permitted Indicati	ons included on Reco	rd						
Indication Requirem	nents							
No Indication Require	ements included on Re	ecord						
Standard Indication	s							
No Standard Indication	ons included on Recor	ď						
Specific Indications	i -							
As a vehicle for many as a sterile irrigation		as an electrolyte reple	enisher for maintenance or re	placement of deficits of e	xtracellular fluid. It car	n also be used		
Warnings								
See Product Informat	tion and Consumer Me	edicine Information for	this product					
Additional Product	information							
Container informati	on							
Туре	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 in	formation							
Pack Size		Poison Schedule						
Carton of 50's		Not scheduled. Not considered by committee						
Carton of 20's		Not scheduled. Not considered by committee						
Components								
1. SODIUM CHLC	RIDE INJECTION BE	0.9%, sodium chlori	de, 10 mL ampoule					
Dosage Form	Injection, s	Injection, solution						
Route of Administ	tration Subcutane Intravenous Intramuscu	S						
Visual Identification	on Clear and o	colourless.						
Active Ingredients	6							
Active ingreaterita								

This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information



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9 mg/mL

sodium chloride

Other Ingredients (Excipients)

hydrochloric acid sodium hydroxide water for injections

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