

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	197200	SODIUM CHLORIDE INJECTION BP 0.9%, sodium chloride, 5 mL ampoule					
ARTG entry for	Medicine Regist	lered					
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 Eva	aluation 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

		N DF 0.9%, 50	dium chloride, 5 mL	ampoule				
Product Type	Single Medicine Product		Effective Date 22/02/202					
Permitted Indications								
No Permitted Indications	included on Record							
ndication Requiremen	ts							
No Indication Requireme	ents included on Reco	rd						
Standard Indications								
No Standard Indications	included on Record							
Specific Indications								
As a vehicle for many pa as a sterile irrigation me		an electrolyte repl	enisher for maintenance or re	placement of deficits of e	extracellular fluid. It can als	o be used		
Warnings								
See Product Information	and Consumer Medio	cine Information for	this product					
Additional Product info	ormation							
Container information								
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 infor	mation							
Pack Size		Poison Schedule						
Carton of 20's			Not scheduled. Not considered by committee					
Components								
1. SODIUM CHLORI	DE INJECTION BP 0.	9%, sodium chlor	ide, 5 mL ampoule					
Dosage Form	Injection, solu	Injection, solution						
Route of Administration	ion Subcutaneous	3						
	Intravenous Intramuscular							
Visual Identification	Clear and cold	ourless.						
Active Ingredients								
sodium chloride	9 mg/ml							
			Produced at 05.08.2022 at 10:54:25 AEST					

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



Australian Government

Department of Health Therapeutic Goods Administration

Other Ingredients (Excipients)

hydrochloric acid sodium hydroxide water for injections

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.

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

This is not an ARTG Certificate document.