

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	198330	WATER FOR INJECTIONS BP, water for injections, 10 mL, solution for injection, 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 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

Product Type	Single Medicine Pr	oduct	Effective Date	14/07/2021					
Permitted Indications	s included on Reco	rd							
ndication Requireme		u .							
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lo Indication Requirem									
	- in cluide de car De com	J							
No Standard Indication	s included on Recor	a							
pecific Indications									
		or dilute substances or p Iring minor surgical proc		dministration. ,Wate	r for Injections BP may also	be used as			
Varnings									
See Product Informatio	n and Consumer Me	edicine Information for th	is product						
Additional Product int	ormation								
Container information	I								
Туре	Material	Life Time	Temperature	Closure	Conditions				
Ampoule	LDPE	24 Months	Store below 25 degrees Celsius	Not recorded	Not recorded				
ack Size/Poison info	rmation								
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. WATER FOR INJ	ECTIONS BP, wate	er for injections, 10 mL	, solution for injection, an	poule					
Dosage Form	Injection, se	Injection, solution							
Route of Administra	tion Intramuscu	lar							
	Intravenous	3							
	Subcutane	ous							
Visual Identification	Clear, colo	Clear, colourless, particle-free							
Active Ingredients									
water for injections	10 mL								
	ge 1 of 2 Produced at 16.07.2021 at 1								

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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This is not an ARTG Certificate document.