

Australian Government

## Department of Health and Aged Care

Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry:	19496	20% OSMITROL Mannitol 100g/500mL injection bag AHB3025				
ARTG entry for	Medicine Registered					
Sponsor	Baxter Healthcare Pty Ltd					
Postal Address	PO Box 88, TOONGABBIE, NSW, 2146 Australia					
ARTG Start Date	30/09/1991					
Product Category	Medicine					
Status	Active					
Approval Area	Drug Safety Ev	valuation Branch				

## Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

## Products

1 . OSMITROL Mannitol 100g/500mL injection AHB3025										
Product Type	Single	Single Medicine Product			Effective Date	13/01/2021				
Permitted Indication	ns									
No Permitted Indicati	ions inclu	ided on Record								
Indication Requiren	nents									
No Indication Requirements included on Record										
Standard Indications										
No Standard Indications included on Record										
Specific Indications										
Osmitrol Intravenous Infusion (Mannitol Intravenous Infusion, BP) can be used in: The promotion of diuresis in the prevention and/or treatment of the oliguric phase of acute renal failure before irreversible renal failure becomes established; The reduction of intraocular pressure when the pressure cannot be lowered by other means; The reduction of intracranial pressure and treatment of cerebral oedema by reducing brain mass and; Promoting the urinary excretion of toxic substances.										
Warnings										
See Product Information and Consumer Medicine Information for this product										
Additional Product information										
Container information										
Туре	Mate	Material Life Time		Tem	Temperature Closure		Conditions			
Bag	Not re	ecorded	2 Years		re below 30 jrees Celsius	Not recorded	Not recorded			
Pack Size/Poison information										
Pack Size		Poison Schedule								
500mL x 1		Not scheduled. Not considered by committee								
Components										
1 . Medicine Com	ponent									
Dosage Form		Injection, solution								
Route of Adminis	tration	Intravenous								
Visual Identificati	on	Clear colourless solution								
Active Ingredient	s									
mannitol		200 g/L								
Other Ingredients	(Excipie	ents)								
hydrochloric acid										
sodium hydroxide	•									
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water for injections

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This is not an ARTG Certificate document.