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 Evaluation 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 Medicine Product **Effective Date** 13/01/2021

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

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

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	Not recorded	2 Years	Store below 30 degrees 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 Component

Dosage Form	Injection, solution
Route of Administration	Intravenous
Visual Identification	Clear colourless solution

Active Ingredients

mannitol	**200 g/L**

Other Ingredients (Excipients)

hydrochloric acid

sodium hydroxide

water for injections

Public Summary