Public Summary

Summary for ARTG Entry:	47410 COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) 1000mL injection bag
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	31/01/1994
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 . COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) 1000mL injection bag

Product Type	Single Medicine Product	**Effective Date**	19/06/2023

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

Compound Sodium Lactate (Hartmann's Solution) Injection is used for intrvenous fluid and electrolyte replacement, as a source of bicarbonate in the treatment of mild to moderate metabolic acidosis associated with dehydration or associated with potassium deficiency, and as a vehicle for intravenous drug delivery, if the drugs are compatible with the solutions.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	Other plastic laminate/Al	3 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1000mL X 1	Not scheduled. Not considered by committee

Components

1 . Medicine Component

Dosage Form	Injection, intravenous infusion
Route of Administration	Intravenous
Visual Identification	Clear, colourless liquid.

Active Ingredients

calcium chloride dihydrate	**.27 g/L**
potassium chloride	**.4 g/L**
sodium chloride	**6 g/L**
sodium lactate	**3.17 g/L**

Public Summary

Other Ingredients (Excipients)

water for injections

Public Summary