Public Summary

Summary for ARTG Entry:	48510 BAXTER COMPOUND SODIUM LACTATE (HARTMAN'S SOLUTION) 1000mL injection BP bag AHB2324
ARTG entry for	Medicine Registered
Sponsor	Baxter Healthcare Pty Ltd
Postal Address	PO Box 88, TOONGABBIE, NSW, 2146 Australia
ARTG Start Date	21/04/1994
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 . BAXTER Compound Sodium Lactate (Hartmann's Solution) 1000mL injection AHB2324

Product Type	Single Medicine Product	**Effective Date**	8/04/2020

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

Is indicated as a source of water and electrolytes. It is also used in patients as a source of bicarbonate in the treatment of mild to moderate metabolic acidosis associated with dehydration or associated with potassium deficiency. These solutions are indicated as methods of intravenous drug delivery, if the drugs are comparable with the solutions.

This product accepted for registration/listing as 'currently supplied' at the time of commencement of the Act. Indications held in ARTG paper records. (Old code)

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	24 Months	Store below 30 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1000mL x 12	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

calcium chloride dihydrate	**270 mg/L**
potassium chloride	**400 mg/L**
sodium chloride	**6 g/L**

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sodium lactate	**3.22 g/L**
Other Ingredients (Excipients)	
lactic acid	
sodium hydroxide	
water for injections	