



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 19425 BAXTER COMPOUND SODIUM LACTATE (HARTMANN'S SOLUTION) 500mL injection BP bag AHB2323

**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"

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 February 1992.

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 February 1992.

### Products

#### 1 . BAXTER Compound Sodium Lactate (Hartmann's Solution) 500mL injection AHB2323

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/04/2020
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#### 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.

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
500mL x 18	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



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potassium chloride	400 mg/L
sodium chloride	6 g/L
sodium lactate	3.22 g/L

**Other Ingredients (Excipients)**

sodium hydroxide  
water for injections

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