# Public Summary

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| **Summary for ARTG Entry:** | 171154 | 3.4% magnesium chloride hexahydrate and 4.8% calcium chloride dihydrate Intravenous Infusion |

| | |
|---|---|
| **ARTG entry for** | Medicine Listed (Export Only) |
| **Sponsor** | Baxter Healthcare Pty Ltd |
| **Postal Address** | PO Box 88, TOONGABBIE, NSW, 2146<br>Australia |
| **ARTG Start Date** | 7/05/2010 |
| **Product Category** | Medicine |
| **Status** | Active |
| **Approval Area** | Export only Medicines |

## Conditions

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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 July 1995, other than condition No. 8 and condition No. 9.

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 July 1995, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

## Products

### 1 . 3.4% magnesium chloride hexahydrate and 4.8% calcium chloride dihydrate Intravenous Infusion

| | | | |
|---|---|---|---|
| **Product Type** | Single Medicine Product | **Effective Date** | 7/05/2010 |

**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**

Calcium and magnesium chloride intravenous infusion is used in conjunction with citrate haemofiltration replacemnet solution, for the replacement of calcium and magnesium

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

| Type | Material | Life Time | Temperature | Closure | Conditions |
|---|---|---|---|---|---|
| Bag | PVC | 12 Months | Store below 30 degrees Celsius | Neither child resistant closure nor restricted flow insert | Do not Freeze |

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|---|---|
| 500mL x 18 | (S1) This Schedule is intentionally blank |

**Components**

**1 .**

| | |
|---|---|
| **Dosage Form** | Injection, intravenous infusion |
| **Route of Administration** | Intravenous |
| **Visual Identification** | clear, colourless solution |

| **Active Ingredients** | |
|---|---|
| **calcium chloride dihydrate** | **24 g/L** |
| **magnesium chloride hexahydrate** | **17 g/L** |

| **Other Ingredients (Excipients)** |
|---|
| **water for injections** |



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