



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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
 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 party 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
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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

Calcium and magnesium chloride intravenous infusion is used in conjunction with citrate haemofiltration replacement 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
500mL x 18

Poison Schedule
(S1) This Schedule is intentionally blank

Components

1.

Public Summary



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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

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