



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|--|
| Summary for ARTG Entry: | 19429 | 6% DEXTRAN 70 in 0.9% SODIUM CHLORIDE 500mL injection bag FKB5013G |
| 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 . 6% Dextran 70 in 0.9% Sodium chloride 500mL injection FKB5013G

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 3/07/2002 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

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)

Specific Indications

No Specific Indications included on Record

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 | Not recorded | Not recorded | Not recorded | Not recorded |

Pack Size/Poison information

| | |
|------------------|--|
| Pack Size | Poison Schedule |
| 500mL x 15 | Not scheduled. Not considered by committee |

Components

1 . Medicine Component

| | |
|--------------------------------|---------------------|
| Dosage Form | Injection, solution |
| Route of Administration | Intravenous |
| Visual Identification | Clear solution |

Active Ingredients

| | |
|-----------------|--------|
| dextran 70 | 60 g/L |
| sodium chloride | 9 g/L |

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Other Ingredients (Excipients)

hydrochloric acid
sodium hydroxide
water for injections

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