



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--|
| Summary for ARTG Entry: | 144814 | WATER FOR INJECTIONS FREEFLEX 1000mL injection bag |
| ARTG entry for | Medicine Registered | |
| Sponsor | Fresenius Kabi Australia Pty Ltd | |
| Postal Address | Level 2, 2 Woodland Way, Mount Kuring-gai, NSW, 2080 Australia | |
| ARTG Start Date | 16/12/2008 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Drug Safety Evaluation Branch | |

Conditions

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.

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.

Products

1 . WATER FOR INJECTIONS FREEFLEX 1000mL injection bag

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 26/10/2020 |
|---------------------|-------------------------|-----------------------|------------|

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

Water for Injections BP is used to dissolve or dilute substances or preparations for parenteral administration. Water for Injections BP may also be used as an irrigating solution for small wounds or during minor surgical procedures.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|------|----------------------------|-----------|--------------------------------|--------------|--------------|
| Bag | Composite plastic laminate | 3 Years | Store below 25 degrees Celsius | Not recorded | Not recorded |

Pack Size/Poison information

| | |
|---------------------------|--|
| Pack Size | Poison Schedule |
| 10 x 1000mL Freeflex bags | Not scheduled. Not considered by committee |

Components

1 . water for injections BP

| | |
|--------------------------------|---------------------------------|
| Dosage Form | Injection, intravenous infusion |
| Route of Administration | Intravenous |
| Visual Identification | Clear, colourless liquid |

Active Ingredients

| | |
|----------------------|---------|
| water for injections | 1000 mL |
|----------------------|---------|

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