

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 144809 WATER FOR INJECTIONS FREEFLEX 500mL 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 500mL 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

Туре	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

20 x 500mL 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 500 mL



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