



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	199953 WATER FOR INJECTIONS B. BRAUN water for injections 10 mL ampoule
<b>ARTG entry for</b>	Medicine Registered
<b>Sponsor</b>	B Braun Australia Pty Ltd
<b>Postal Address</b>	PO Box 6221, BAULKHAM HILLS DC, NSW, 2153 Australia
<b>ARTG Start Date</b>	4/09/2013
<b>Product Category</b>	Medicine
<b>Status</b>	Active
<b>Approval Area</b>	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 B. BRAUN water for injections 10 mL ampoule**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	12/12/2013
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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**

Water for injections is used for the reconstitution and preparation of aqueous injections

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	LDPE	3 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
20 x 10 mL	Not scheduled. Not considered by committee

**Components**

**1 . WATER FOR INJECTIONS B. BRAUN water for injections 10 mL**

<b>Dosage Form</b>	Injection, solvent for
<b>Route of Administration</b>	Intramuscular Subcutaneous Intravenous Infusion
<b>Visual Identification</b>	Clear, particle free, colourless sterile liquid

**Active Ingredients**

<b>water for injections</b>	<b>10 mL</b>
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