



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	279137	Chlorhexidine Irrigation Solution 0.1%
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Pfizer (Perth) Pty Ltd	
Postal Address	PO Box 1007, BENTLEY DC, WA, 6983 Australia	
ARTG Start Date	15/08/2016	
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 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 . Chlorhexidine Irrigation Solution 0.1%

Product Type	Single Medicine Product	Effective Date	15/08/2016
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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

For skin, cavity and wound irrigation/dressing.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	LDPE	2 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
30 mL x 30	(S1) This Schedule is intentionally blank

Components

1 .

Dosage Form	Solution
Route of Administration	Topical
Visual Identification	Clear, blue aqueous solution, free from visible impurities.

Active Ingredients



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chlorhexidine gluconate

1 mg/mL

Other Ingredients (Excipients)

methylene blue

nonoxinol 8

water for injections

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