

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 329547 BAXTER Chlorhexidine Acetate 0.05% aqueous antiseptic solution bottle

ARTG entry for Medicine Listed (Export Only)

Sponsor Baxter Healthcare Pty Ltd

Postal Address PO Box 88, TOONGABBIE, NSW, 2146

Australia

ARTG Start Date 6/02/2020
Product Category Medicine
Status Active

Approval Area Export only Medicines

Conditions

Except where the sponsor has been contracted by an overseas partry 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. BAXTER Chlorhexidine Acetate 0.05% aqueous antiseptic solution bottle

Product Type Single Medicine Product Effective Date 6/02/2020

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

Chlorhexidine Acetate (0.5%) antiseptic solution is used as a general antiseptic. It is used for the cleaning and disinfecting of wounds and the antiseptic treatment of burns.

Warnings

No Warnings included on Record

Additional Product information

Container information

 Type
 Material
 Life Time
 Temperature
 Closure
 Conditions

 Bottle
 Not recorded
 24 Months
 Store below 30 degrees Celsius
 Not recorded
 Protect from Light

Pack Size/Poison information

Pack Size Poison Schedule

Components

1.

Dosage FormSolutionRoute of AdministrationTopical

Visual Identification Clear, slightly blue solution

Active Ingredients

chlorhexidine acetate .5 mg/mL

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Other Ingredients (Excipients)

glacial acetic acid methylene blue water for injections

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