1 PRODUCT NAME

Chlorhexidine Acetate 0.05% (0.05%, solution, antiseptic).
Chlorhexidine Acetate 0.1% (0.1%, solution, antiseptic).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients
Chlorhexidine acetate BP 0.05% w/v and 0.1% w/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Antiseptic solution.

Physical Characteristics
Chlorhexidine Acetate 0.05% and **Chlorhexidine Acetate 0.1%** antiseptic solutions are clear, slightly blue sterile solutions.

The solutions are hypotonic and are haemolytic.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Chlorhexidine Acetate antiseptic solutions are used as a general antiseptic. They are used for the cleaning and disinfecting of wounds and the antiseptic treatment of burns.

4.2 Dose and Method of Administration

Dosage
As required to disinfect wound area. See *Directions For Use.* Dosage and duration of administration are to be individualized and depend upon the indication for use, the patient's ages, weight, clinical condition, concomitant treatment and on patient's clinical response to treatment (see section 4.4).

Not for intravenous or oral route of administration.

Product should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. Do not use unless the solution is clear and the seal is intact.

Directions For Use
The area where **Chlorhexidine Acetate** antiseptic solution is to be used should be rinsed thoroughly with water. Apply the minimum amount necessary to cover the wound area and wash gently. Leave the area to dry by air for 3 minutes.

Discard within 24 hours of opening.

This solution is used as a general antiseptic, and is also recommended for disinfection of respirators.

To Open
Hold Steripour® bottle and twist lid to open, breaking the tamper proof seal.

4.3 Contraindications

Known hypersensitivity to chlorhexidine acetate or methylene blue or to any of the excipients listed in section 6.1.

Chlorhexidine acetate antiseptic solutions should not be used in the eye, intravenously, orally, in the auditory canal (especially perforated eardrums) or near meninges, brain or spinal cord.

4.4 Special Warnings and Precautions For Use

General

- Chlorhexidine Acetate antiseptic solution is used as a topical solution; it should not be used intravenously or taken orally. Do not swallow. If swallowed seek urgent medical attention.
- It should not be used if you have a history of allergy to any of the ingredients of Chlorhexidine Acetate antiseptic solution.
- The use of chlorhexidine as a mouthwash has been associated with reversible discolouration of the tongue, teeth, and silicate or composite dental restorations.
- It should not be used if the expiry date printed on the label is overdue. Do not use unless the solution is clear, free of particles and the tamper proof seal is intact.

Hypersensitivity Reactions

- Hypersensitivity reactions including anaphylactic/anaphylactoid reactions have been reported with chlorhexidine acetate. Fatal anaphylactic reactions have been reported with other products containing chlorhexidine acetate.
- If any signs or symptoms of a suspected hypersensitivity reaction develop, immediately stop using the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Chemical Burns in Neonates

- The use of chlorhexidine acetate solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with skin reactions such as chemical burns in neonates. Based on available case reports in the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.
- Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to chlorhexidine acetate solutions, care must be taken to ensure no excess product is present prior to application of the dressing.

Preoperative Skin Preparation

Chlorhexidine acetate should not be used in preoperative skin preparations for face or head.

Chlorhexidine acetate must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that chlorhexidine does not migrate beyond its intended application site into the eyes. Particular care should be taken in anesthetized patients, who are unable to immediately report ocular exposure. If chlorhexidine comes into contact with the eyes, wash out

promptly and thoroughly with water. An ophthalmologist's advice should be sought.

Use in the Elderly
No data available.

Paediatric Use
This product is safe for use on children.

The use of chlorhexidine solutions has been associated with skin reactions such as chemical burns in neonates.

Effects on Laboratory Tests
The effect of this medicine on laboratory tests has not been established.

4.5 Interaction with Other Medicines and Other Forms of Interaction
The action of chlorhexidine acetate is reduced by an alkaline pH, the presence of organic matter, anionic detergents and tannins.

For incompatibilities see section 6.2.

4.6 Fertility, Pregnancy and Lactation
Fertility
The effects of chlorhexidine acetate on human reproduction have not been studied.

Pregnancy (Category A)
The "Prescribing Medicines in Pregnancy" booklet categorises chlorhexidine as a Category A medicine.

Breast-feeding
This product is safe for use in lactation.

4.7 Effects on Ability to Drive and Use Machines
The effects of Chlorhexidine Acetate antiseptic solution on a person's ability to drive and use machines were not assessed as part of registration.

4.8 Undesirable Effects
Anaphylactic/anaphylactoid reactions to chlorhexidine acetate have been reported. Manifestations of such reactions have included cardiac arrest, circulatory collapse, hypotension, bronchospasm, rash, erythema, tachycardia, urticaria and shock. Fatal anaphylactic reaction has been reported.

Some patients may experience skin irritation or an allergic reaction/hypersensitivity reactions on contact with this product. If this occurs, the use of this product should be stopped immediately. Skin sensitivity to chlorhexidine acetate has occasionally been reported.

Very occasionally the following reactions have been noted when chlorhexidine acetate containing irrigating solutions have been used intravesically, intravaginally or topically on traumatised skin: hypotension, paraesthesia, dyspnoea, tachycardia cold sweat, generalized erythema, urticaria and loss of consciousness.

Strong solutions may cause irritation of the conjunctiva and other sensitive tissues. Transient taste

disturbances and burning sensation of the tongue may occur on initial use.

Oral desquamation and occasional parotid gland swelling have been reported with the mouthwash. If desquamation occurs, a 50% dilution of the mouthwash with water and less vigorous rinsing may allow continued use.

The adverse events reported and/or observed with other chlorhexidine products include:

- Fatal anaphylactic reactions
- Chemical burns in neonates (see section 4.4).
- Eye Disorder: Frequency not known: Corneal erosion, corneal epithelium defect/ injury corneal, visual impairment*

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

Chlorhexidine acetate is poorly absorbed by the gastrointestinal tract. If ingested, advice concerning treatment should be sought immediately from a doctor.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: Blood and Blood Forming Organs/Blood Substitutes and Perfusion Solutions/Irrigating Solutions/Antiinfectives/Chlorhexidine

ATC Code: B05CA02.

Chemical Name: 1,1-hexamethylenebis[4-(4-chlorophenyl)biguanide] diacetate.

Molecular Formula: $C_{22}H_3OCl_2N_{10}2C_2H_4O_2$

Molecular Weight: 626

Appearance: White or almost white, microcrystalline powder.

CAS Numbers: Chlorhexidine Acetate 56-95-1

Mechanism of Action

Chlorhexidine Acetate antiseptic solutions are used as topical solutions.

Clinical Trials

No data available.

5.2 Pharmacokinetic Properties

No data available.

5.3 Preclinical Safety Data

Genotoxicity

Studies with chlorhexidine acetate have not been performed to evaluate mutagenic potential.

Carcinogenicity

Studies with chlorhexidine acetate have not been performed to evaluate carcinogenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Inactive Ingredients:

Methyl blue, Glacial acetic acid and Water for Injections BP.

6.2 Incompatibilities

Prolonged immersion of rubber appliances in these solutions should be avoided. Chlorhexidine is incompatible with soaps, other anionic materials and with potassium iodide.

6.3 Shelf Life

24 months. The expiry date can be found on the packaging.

6.4 Special Precautions for Storage

Please see following table for specific storage conditions for Chlorhexidine Acetate antiseptic solutions. Do not heat in excess of 80°C. Protect from light.

6.5 Nature and Contents of Container

Chlorhexidine Acetate antiseptic solutions are supplied in the pack sizes listed in the following table. They are packaged in plastic pour bottles, sealed with tamper proof lids.

Strength	Pack size*	Storage requirements	Product Code	TT50-
Chlorhexidine Acetate 0.05%	100mL	Store below 30°C	AHF7977	3229
Chlorhexidine Acetate 0.05%	500mL	Store below 30°C	AHF7983	3229
Chlorhexidine Acetate 0.05%	1000mL	Store below 30°C	AHF7984	3229
Chlorhexidine Acetate 0.1%	100mL	Store below 30°C	AHF7978	3229/2
Chlorhexidine Acetate 0.1%	500mL	Store below 25°C	AHF7985	3229/2
Chlorhexidine Acetate 0.1%	1000mL	Store below 25°C	AHF7986	3229/2

*Not all pack sizes may be marketed.

6.6 Special Precautions for Disposal and Handling

Any unused product or waste material should be disposed of in accordance with local requirements. Do not heat Steripour® bottle in excess of 80°C.

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Chlorhexidine Acetate antiseptic solutions are distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060
Phone (09) 574 2400.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Chlorhexidine Acetate antiseptic solutions are distributed in Australia by:

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie
NSW 2146.

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:

Chlorhexidine Acetate 0.05% antiseptic solution: 11 March 1982.
Chlorhexidine Acetate 0.1% antiseptic solution: 11 March 1982.

10 DATE OF REVISION OF THE TEXT

19 December 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	All sections updated to streamline headings, formatting, use of trade name All sections updated for consistency with information in Chlorhexidine Acetate with Cetrimide data sheet.
4.4	Added warning on preoperative skin preparation Included subheadings: Use in Elderly and Effects on Laboratory Tests.
4.5	Included reference to section 6.2
4.8	Added adverse effects: Fatal anaphylactic reactions and eye disorder. Updated AE reporting URL.
5.1	Section updated.
5.3	Section updated.
6.3	Section updated to refer to expiry date on packaging.

Based on Australian PI most recent amendment 5 September 2024.

*Please refer to the Medsafe website (**www.medsafe.govt.nz**) for most recent data sheet.*