1 PRODUCT NAME

Chlorhexidine Acetate 0.015% Cetrimide 0.15% antiseptic solution.
Chlorhexidine Acetate 0.05% Cetrimide 0.5% antiseptic solution.
Chlorhexidine Acetate 0.1% Cetrimide 1% antiseptic solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

Chlorhexidine acetate BP 0.015%w/v, 0.05%w/v, 0.1%w/v; and
Cetrimide 0.15%w/v, 0.5%w/v, 1%w/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Antiseptic solution.

Physical Characteristics

Chlorhexidine Acetate 0.015% Cetrimide 0.15%, Chlorhexidine Acetate 0.05% Cetrimide 0.5%, and **Chlorhexidine Acetate 0.1% Cetrimide 1%** antiseptic irrigation solutions are yellow sterile solutions.

The solutions are hypotonic and are haemolytic.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine Acetate with Cetrimide antiseptic solutions are used as a general antiseptic. They are used for the cleaning and disinfecting of wounds as an antiseptic treatment for 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 with Cetrimide** 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.

Use undiluted. Do not mix with detergents or other chemicals. Discard within 24 hours of opening. The solution is used for cleaning and disinfecting wounds and as an antiseptic treatment for burns.

To Open

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

4.3 Contraindications

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

Chlorhexidine Acetate with Cetrimide antiseptic solution 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 with Cetrimide antiseptic solution is used as a topical solution; it must not be used intravenously, or taken orally. Do not swallow. If swallowed seek urgent medical attention. If ingested, cetrimide may cause nausea and vomiting. Swallowing this solution may cause oesophageal damage or necrosis. Demulcents may be given, but emesis and lavage should be avoided.
- It should not be used if you have a history of allergy to any of the ingredients of Chlorhexidine Acetate with Cetrimide 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.
- This product should not be used in body cavities or as an enema. It should not be used for the disinfection of soft contact lenses.
- Accidental intra-uterine or intravenous administration may cause haemolysis.
- 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 tamperproof seal is intact.

Hypersensitivity Reactions

- Hypersensitivity reactions including anaphylactic/anaphylactoid reactions have been reported with chlorhexidine. 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 use the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Some patients become hypersensitive to cetrimide after repeated applications.

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 the face and 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 with Cetrimide antiseptic solution on a person's ability to drive and use machines were not assessed as part of its 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, 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 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 a 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

If taken by mouth, cetrimide and other quaternary ammonium compounds cause nausea and vomiting. 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

	Chlorhexidine acetate	Cetrimide
Pharmacotherapeutic group	Blood and Blood Forming Organs/Blood Substitutes and Perfusion Solutions/Irrigating Solutions/Antiinfectives/Chlorhexidine	Dermatologicals, Antiseptics and Disinfectants, Antiseptics And Disinfectants, Quaternary Ammonium Compounds
ATC code	B05CA02.	D08AJ04
Chemical names	1,1-hexamethylenebis[4-(4- chlorophenyl) biguanide] diacetate,	trimethyltetraecylammonium bromide
Molecular formula	$C_{26}H_{38}Cl_2N_{10}O_4$	$C_{17}H_{38}BrN$
Molecular weight	626	336.4
Appearance	White to almost white, microcrystalline powder	White or almost white, voluminous, free-flowing powder
Solubility	Sparingly soluble in water, soluble in ethanol (96 per cent), slightly soluble in glycerol and in propylene glycol.	Freely soluble in water and in alcohol.
CAS Numbers	56- 95-1	505-86-2

Mechanism of Action

Cetrimide is a quaternary ammonium antiseptic with actions and uses typical of cationic surfactants. These surfactants dissociate in aqueous solution into a relatively large and complex cation, which is responsible for the surface activity, and a smaller inactive anion. In addition to emulsifying and detergent properties, quaternary ammonium compounds have bactericidal activity against Gram-positive and, at the higher concentrations, against some Gram-negative bacteria. Some *Pseudomonas spp*. are particularly resistant as are strains of *Mycobacterium tuberculosis*. They are ineffective against bacterial spores, have variable antifungal activity, and are effective against some viruses.

Quaternary ammonium compounds are most effective in neutral or slightly alkaline solutions and their bactericidal activity is appreciably reduced in acid media; alcohols enhance their activity.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

Not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive Ingredients:

Tartrazine Cl 19140, Glacial acetic acid & 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

Chlorhexidine Acetate with Cetrimide antiseptic solutions should be stored below 30°C. Do not heat in excess of 80°C. Protect from light.

6.5 Nature and Contents of Container

Chlorhexidine Acetate with Cetrimide antiseptic solutions are supplied in 3 strengths and in the pack sizes listed in the following table. They are packaged in plastic pour bottles, sealed with tamper proof lids.

Strength	Pack size*	Product code	TT50-
Chlorhexidine acetate 0.015% Cetrimide 0.15%	100mL	AHF7971	3230/1
Chlorhexidine acetate 0.015% Cetrimide 0.15%	500mL	AHF7970	3230/1
Chlorhexidine acetate 0.015% Cetrimide 0.15%	1000mL	AHF7969	3230/1
Chlorhexidine acetate 0.05% Cetrimide 0.5%	100mL	AHF7979	3230
Chlorhexidine acetate 0.05% Cetrimide 0.5%	500mL	AHF7988	3230
Chlorhexidine acetate 0.05% Cetrimide 0.5%	1000mL	AHF7987	3230
Chlorhexidine acetate 0.10% Cetrimide 1.0%	100mL	AHF7973	3230/2
Chlorhexidine acetate 0.10% Cetrimide 1.0%	500mL	AHF7972	3230/2
Chlorhexidine acetate 0.10% Cetrimide 1.0%	1000mL	AHF7968	3230/2

*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 with Cetrimide 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 with Cetrimide 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 0.015% Cetrimide 0.15% antiseptic solution 28 April 1986.
Chlorhexidine acetate 0.05% Cetrimide 0.5% antiseptic solution 28 April 1986.
Chlorhexidine acetate 0.1% Cetrimide 1% antiseptic solution 28 April 1986.

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 data sheet.
4.2	Section updated so text is consistent with Chlorhexidine Acetate data sheet.
4.4	Section rearranged for consistency with Chlorhexidine Acetate data sheet, and 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: cardiac arrest, circulatory collapse, Fatal anaphylactic reactions and eye disorder. Updated AE reporting URL.
5.1, 5.2, 5.3	Sections updated for consistency with Chlorhexidine Acetate data sheet.
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.