

NEW ZEALAND DATA SHEET

1 CHLORHEXIDINE ACETATE WITH CETRIMIDE, ANTISEPTIC SOLUTIONS

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%, Chlorhexidine acetate 0.1% Cetrimide 1% antiseptic irrigation solutions are yellow sterile solutions.

The solutions are hypotonic and haemolytic.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine acetate with Cetrimide antiseptic solution is used as a general antiseptic. It is 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.

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.

To open

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

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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

Chlorhexidine acetate with Cetrimide antiseptic solution should not be used intravenously or taken orally.

This product should not be used in body cavities or as an enema. Chlorhexidine should not be used in preoperative skin preparations for the face and head. It should not be used for the disinfection of soft contact lenses.

The use of chlorhexidine 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, care must be taken to ensure no excess product is present prior to application of the dressing.

Seek urgent medical attention if **Chlorhexidine acetate with Cetrimide** antiseptic solution is swallowed. 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.

Accidental intra-uterine or intravenous administration may cause haemolysis.

It should not be used if you have a history of allergy to any of the ingredients of **Chlorhexidine acetate with Cetrimide** antiseptic solution.

Some patients become hypersensitive to cetrimide after repeated applications. 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 tamperproof seal is intact.

Paediatric Use

This product is safe for use on children.

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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.

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

Chlorhexidine acetate with Cetrimide antiseptic solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Anaphylactic/anaphylactoid reactions to chlorhexidine have been reported. Manifestations of such reactions have included 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 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.

Chemical burns in neonates have been reported with similar chlorhexidine solutions (see section 4.4).

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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://nzphvc.otago.ac.nz/reporting/>

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 or 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
<i>Pharmacotherapeutic group</i>	Blood and Blood Forming Organs/Blood Substitutes and Perfusion Solutions/Irrigating Solutions/Anti-infectives/Chlorhexidine	Dermatologicals, Antiseptics and Disinfectants, Antiseptics And Disinfectants, Quaternary Ammonium Compounds
<i>ATC code</i>	B05CA02.	D08AJ04
<i>CAS Numbers</i>	Chlorhexidine 55-56-1 Acetate 56-95-1	505-86-2
<i>Chemical names</i>	1,1-hexamethylenebis[4-(4-chlorophenyl) biguanide] diacetate,	trimethyltetraethylammonium bromide
<i>Molecular formula</i>	C ₂₂ H ₃₀ Cl ₂ N ₁₀ O ₂	C ₁₇ H ₃₈ BrN

Chlorhexidine acetate with Cetrimide antiseptic solution is used as a topical solution; it must not be administered intravenously.

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.

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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.

5.2 Pharmacokinetic properties

Chlorhexidine acetate with Cetrimide antiseptic solution is used as a topical solution.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive Ingredients:

Tartrazine CI 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.

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 solution is supplied in 3 strengths.

Each strength has 3 sizes (see the following table).

Strength	Pack	Product	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.

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6.6 Special precautions for disposal and handling

Any unused medicine 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 Cetrимide antiseptic solutions are distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

Chlorhexidine acetate with Cetrимide 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% Cetrимide 0.15% antiseptic solution 28 April 1986.

Chlorhexidine acetate 0.05% Cetrимide 0.5% antiseptic solution 28 April 1986.

Chlorhexidine acetate 0.1% Cetrимide 1% antiseptic solution 28 April 1986.

10 DATE OF REVISION OF THE TEXT

20 October 2020.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Tradename(s) updated.

Based on Australian PI approved 30 September 1991; most recent amendment 19 February 2015; and RSI 2014 1125.

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

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