AUSTRALIAN PRODUCT INFORMATION – CHLORHEXIDINE AND CETRIMIDE IRRIGATION SOLUTION (CHLORHEXIDINE GLUCONATE AND CETRIMIDE)

1. NAME OF THE MEDICINE

Chlorhexidine gluconate and Cetrimide.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 4.5 mg/30 mL (0.015% w/v) and cetrimide 45 mg/30 mL (0.15% w/v).

Chlorhexidine gluconate 15 mg/30 mL (0.05% w/v) and cetrimide 150 mg/30 mL (0.5% w/v).

3. PHARMACEUTICAL FORM

Sterile, orange coloured irrigation solution containing chlorhexidine gluconate and cetrimide in purified water. The colouring agent is sunset yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For cleansing and irrigating the skin and dirty wounds where an added surfactant effect is required.

4.2 Dose and method of administration

Rinse the area to be cleaned with water, apply the minimum amount of irrigation necessary to cover the wound area and wash gently. Rinse again thoroughly. Apply to wound as necessary. Discard remaining solution after use.

4.3 Contraindications

Known hypersensitivity to either chlorhexidine or cetrimide.

Do not use to irrigate the brain, meninges, eyes or perforated eardrum.

4.4 Special warnings and precautions for use

For external use only. Not for injection, for irrigation only. Not isotonic and is haemolytic.

Cetrimide may have a prolonging effect on the wound healing process. Use of this antiseptic should be restricted to infection control and cleansing of wounds rather than general wound management.

Use in the elderly

No data available.

Paediatric use

Use with care in neonates, particularly in premature infants. Chlorhexidine may cause irritation or chemical burns.

Effects on laboratory tests

No data available.

4.5 Interactions with other medicines and other forms of interactions

No data available.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Use in pregnancy

No data available.

Use in lactation

No data available.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (undesirable effects)

Irritative skin reactions and hypersensitivity reactions to chlorhexidine have been reported. In the event that these reactions occur, discontinue use.

Chlorhexidine may cause anaphylactic reaction.

Cetrimide may have a prolonging effect on the wound healing process.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 Overdose

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Chlorhexidine: Chlorhexidine is an antiseptic and disinfectant which is effective against a wide range of vegetative Gram-positive and Gram-negative organisms, some viruses and some fungi. It is ineffective against bacterial spores at room temperature, and acid-fast bacteria are inhibited but not killed. It is more active against Gram-positive than Gram-negative bacteria and some species of *Pseudomonas* and *Proteus* are relatively less susceptible. Chlorhexidine is most active at a neutral or slightly acid pH and its activity may be reduced by blood and other organic matter.

Cetrimide: Cetrimide is a quaternary ammonium disinfectant with properties typical of cationic surfactants. Solutions of these surfactants have emulsifying and detergent properties and bactericidal activity against both Gram-positive and Gram-negative organisms but higher concentrations are necessary to kill the latter. The combined detergent and antibacterial properties of cetrimide make it useful in cleansing dirty or infected wounds. It is however, relatively ineffective against bacterial spores, acid-fast bacteria, viruses and fungi.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water.

Sunset yellow FCF.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store below 25°C. Protect from light. Single use only. Discard unused portion.

6.5 Nature and contents of container

Chlorhexidine 0.015% cetrimide 0.15% irrigation solution, 30 mL Steritube® ampoule

Chlorhexidine 0.05% cetrimide 0.5% irrigation solution, 30 mL Steritube® ampoule

Pack size: 30 units.

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

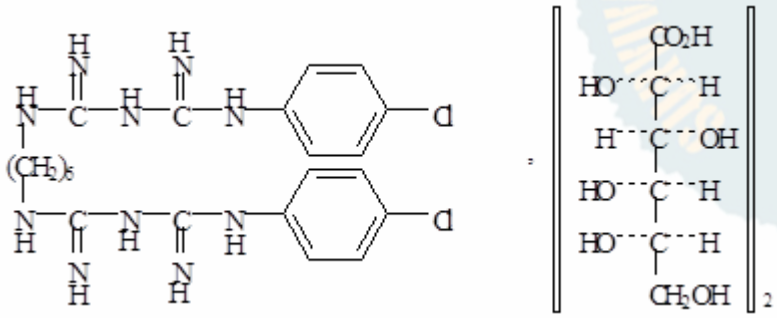
6.7 Physicochemical properties

Chlorhexidine gluconate

The active ingredient chlorhexidine gluconate solution is an almost colourless or pale yellowish liquid. It is miscible with water, soluble in acetone and in ethanol (96%).

Chemical structure

The structural formula is represented below:



Molecular Formula: $C_{22}H_{30}Cl_2N_{10},2C_6H_{12}O_7$

Molecular Weight: 898

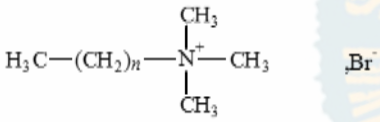
CAS number

18472-51-0

Cetrimide

The active ingredient cetrimide is a white or almost white voluminous free-flowing powder, which has a slight and characteristic odour. It is freely soluble in water, chloroform and ethanol (96%) and practically insoluble in ether. The structural formula is represented below:

Chemical structure



Molecular Formula: $C_{17}H_{38}BrN$

Molecular Weight: 336.4

CAS number

505-86-2

7. MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

9. DATE OF FIRST APPROVAL

4 September 1996

10. DATE OF REVISION

16 March 2020

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Summary Table of Changes

Section changed	Summary of new information
All	All sections reformatted in line with the new form.
4.8	Update to include anaphylactic reaction to chlorhexidine.
8	Sponsor address and information updated.