

AUSTRALIAN PRODUCT INFORMATION – CHLORHEXIDINE IRRIGATION SOLUTION (CHLORHEXIDINE GLUCONATE)

1. NAME OF THE MEDICINE

Chlorhexidine gluconate.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 30 mg/30 mL (0.1% w/v).

Chlorhexidine gluconate 60 mg/30 mL (0.2% w/v).

3. PHARMACEUTICAL FORM

Sterile blue coloured irrigation solution containing chlorhexidine gluconate in water for injections. The colouring agent is methylene blue. Chlorhexidine Irrigation Solution 0.1% w/v contains octoxinol 8 as a wetting agent.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine Irrigation Solution 0.1% w/v

For skin and wound irrigation or dressing to prevent and control infection.

Chlorhexidine Irrigation Solution 0.2% w/v

For antisepsis of external genitalia prior to catheterisation of the bladder.

4.2 Dose and method of administration

Chlorhexidine Irrigation Solution 0.1% w/v

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.

Chlorhexidine Irrigation Solution 0.2% w/v

Irrigate the area of the external genitalia thoroughly prior to catheterisation.

4.3 Contraindications

Known hypersensitivity to chlorhexidine.

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

Do not use in body cavities or as enema.

4.4 Special warnings and precautions for use

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

Not to be used as a preoperative skin preparation for face or head.

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 – Pregnancy Category A

Chlorhexidine has been used by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Based on negligible topical absorption and a complete lack of any unusual reported effects when used during pregnancy, chlorhexidine would not appear to present a risk to pregnant women. No special precautions or changes in methods of application or use of chlorhexidine seem needed in pregnant health care workers or patients.

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 anaphylaxis.

Hematuria has been reported following bladder irrigation.

There have been at least four cases of irreversible corneal damage due to contact with chlorhexidine. Chlorhexidine has been reported to cause deafness when instilled into the middle ear through a perforated eardrum.

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).

Symptoms and treatment

In case of accidental or deliberate oral poisoning or ingestion

Chlorhexidine taken orally is poorly absorbed. Immediate dilution with (120 - 240 mL) water or milk (not to exceed 15 mL/kg in children) is recommended. The administration of charcoal is not likely to be beneficial and may obscure visualisation during endoscopy. It is not recommended unless other substances known to be absorbed to charcoal are co-ingested. Employ supportive measures as appropriate.

In case of accidental intravenous administration

Haemolysis due to hypotonicity has been reported. Blood transfusion may be necessary to counteract haemolysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

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.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

Chlorhexidine is not teratogenic in rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorhexidine Irrigation Solution 0.1% w/v

Methylene blue

Octoxinol 8

Water for injections

Chlorhexidine Irrigation Solution 0.2% w/v

Methylene blue

Water for injections

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 0.1% irrigation solution, 30 mL (sterile) Steritube[®] ampoule.

Chlorhexidine 0.2% irrigation solution, 30 mL (sterile) Steritube[®] ampoule.

Pack size: 30 units.

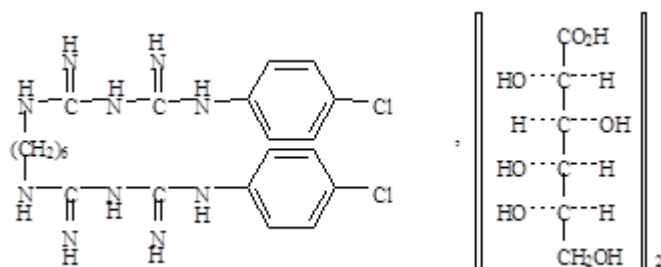
6.6 Special precautions for disposal

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

6.7 Physicochemical properties

Chlorhexidine gluconate solution is an almost colourless or pale yellowish liquid. It is miscible with water, soluble in acetone and in alcohol. The structural formula of chlorhexidine gluconate is represented below:

Chemical structure



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

Molecular Weight: 898

CAS number

18472-51-0

7. MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Toll Free Number: 1800 675 229
www.pfizer.com.au

9. DATE OF FIRST APPROVAL

13 August 1991

10. DATE OF REVISION

25 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.
8	Sponsor address and information updated