

PRODUCT INFORMATION

Chlorhexidine Irrigation Solution

NAME OF THE MEDICINE

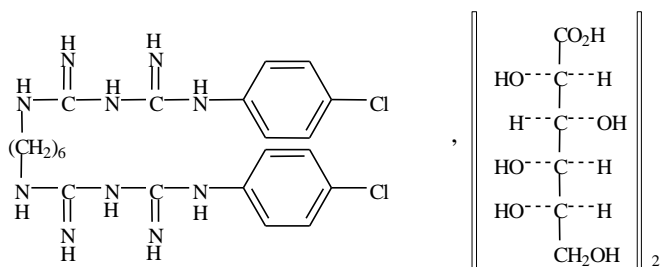
Chlorhexidine Gluconate Solution BP.

DESCRIPTION

Chlorhexidine Irrigation Solutions are sterile blue coloured solutions for irrigation containing Chlorhexidine Gluconate Solution BP in Water for Injections BP. The colouring agent is methylene blue.

Chlorhexidine Irrigation Solution 0.1% w/v contains octoxinol 8 as a wetting agent.

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:



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

Molecular Weight: 898

CAS Number: 18472-51-0

PHARMACOLOGY

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.

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

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.

PRECAUTIONS

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 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.

Paediatric Use

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

Carcinogenicity

Chlorhexidine is not teratogenic in rats.

ADVERSE 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.

DOSAGE AND 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.

OVERDOSAGE

If poisoning occurs, contact a doctor or Poisons Information Centre.

Symptoms and treatment

In case of accidental or deliberate oral poisoning or ingestion

Chlorhexidine taken orally is poorly absorbed. Immediate dilution with (120 - 240mL) water or milk (not to exceed 15mL/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.

PRESENTATION AND STORAGE CONDITIONS

Chlorhexidine Irrigation Solution 0.1% w/v 30mL (sterile) Steritube®

Chlorhexidine Irrigation Solution 0.2% w/v 30mL (sterile) Steritube® (Not available in New Zealand)

Note: All above irrigation solutions are tinted blue.

Storage

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

The expiry date (month/year) is stated on the package after the word EXP.

NAME AND ADDRESS OF THE SPONSOR**Sponsor in Australia**

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114 Australia

Manufacturer

Pfizer (Perth) Pty Ltd

ABN 32 051 824 956

15 Brodie Hall Drive

Bentley WA 6102 Australia

POISON SCHEDULE OF THE MEDICINE

Australia – Not scheduled.

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

13 August 1991

DATE OF MOST RECENT AMENDMENT

18 July 2016

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