

PRODUCT INFORMATION

Chlorhexidine and Cetrime Irrigation Solution

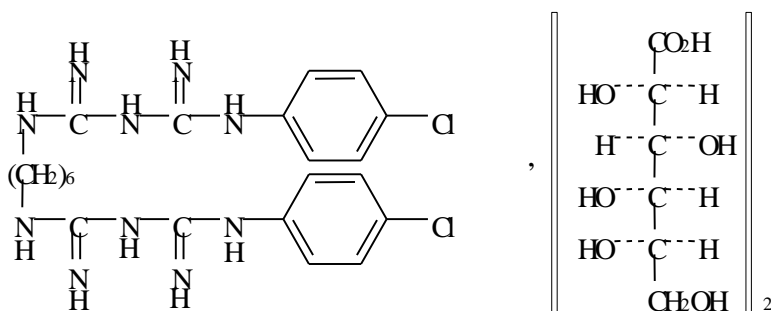
NAME OF THE MEDICINE

Chlorhexidine Gluconate Solution and Cetrime

DESCRIPTION

Chlorhexidine and Cetrime Irrigation Solutions are sterile, orange coloured solutions containing Chlorhexidine Gluconate Solution and Cetrime in Water - Purified. The colouring agent is sunset yellow.

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%). The structural formula is represented below:

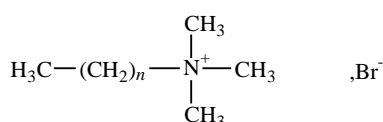


Molecular Formula: $C_{22}H_{30}Cl_2N_{10}, 2C_6H_{12}O_7$

Molecular Weight: 898

CAS Number: 18472-51-0

The active ingredient cetrime 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:



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

Molecular Weight: 336.4

CAS Number: 505-86-2

PHARMACOLOGY

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.

INDICATIONS

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

CONTRAINDICATIONS

Known hypersensitivity to either chlorhexidine or cetrimide.

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

PRECAUTIONS

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.

Paediatric Use

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

ADVERSE EFFECTS

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

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

DOSAGE AND 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.

OVERDOSAGE

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

PRESENTATION AND STORAGE CONDITIONS

Chlorhexidine and Cetrime Irrigation Solution 30mL Steritube® ampoule (chlorhexidine gluconate 0.015% w/v and cetrime 0.15% w/v)

Chlorhexidine and Cetrime Irrigation Solution 30mL Steritube® ampoule (chlorhexidine gluconate 0.05% w/v and cetrime 0.5% w/v)

Note: All above irrigation solutions are tinted orange.

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 Limited
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia

Manufacturer

Pfizer (Perth) Pty Limited
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

4 September 1996

DATE OF MOST RECENT AMENDMENT

18 July 2016

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