CHLORHEXIDINE ACETATE WITH CETRIMIDE (%) ANTISEPTIC SOLUTION

NAME OF THE MEDICINE

Proprietary name: Baxter Chlorhexidine Cetrimide Antiseptic Solution
Non-proprietary name: Chlorhexidine Acetate with Cetrimide Irrigating Solution
Chemical Name: Chlorhexidine (CAS number: 55-56-1) and Acetate (CAS number: 56-95-1) is a 1,1-hexamethylenebis[4-(4-chlorophenyl)biguanide] diacetate, and Cetrimide (CAS number 505-86-2) is trimethyltetraecylammonium bromide
Molecular formula: C_{22}H_{3}OCl_{2}N_{10}2C_{2}H_{4}O_{2} and C_{17}H_{38}BrN.

DESCRIPTION

Chlorhexidine Acetate (0.015%, 0.05% and 0.1%) with Cetrimide Antiseptic Solutions are yellow sterile solutions.

Active Ingredients: Chlorhexidine Acetate BP 0.015% w/v, 0.05% w/v and 0.1% w/v and Cetrimide 0.15% w/v, 0.5% w/v and 1.0% w/v.
Inactive Ingredients: Tartrazine Cl 19140, glacial acetic acid and water for injections BP.

The solution is used for cleaning and disinfecting wounds and as an antiseptic treatment for burns. The solution is hypotonic and haemolytic. It is supplied in 3 strengths. Each strength is supplied in 3 sizes (see Table 1).

PHARMACOLOGY

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.

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.
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.

CONTRAINDICATIONS

Known hypersensitivity to chlorhexidine or cetrimide. 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.

PRECAUTIONS

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.

**Incompatibility**

Prolonged immersion of rubber appliances in these solutions should be avoided. Chlorhexidine is incompatible with soaps, other anionic materials and with potassium iodide.

**Use in Pregnancy Category A**

The “Prescribing Medicines in Pregnancy” booklet categorises chlorhexidine as a Category A medicine.

**Use in Lactation**

This product is safe for use in lactation.

**Paediatric Use**

This product is safe for use on children.

**INTERACTIONS WITH OTHER MEDICINES**

The action of chlorhexidine is reduced by an alkaline pH, the presence of organic matter, anionic detergents and tannins.

**ADVERSE 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 PRECAUTIONS)

**DOSAGE AND 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.

**OVERDOSAGE**
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 contact the Poison Information Centre on 131126.

**PRESENTATION AND STORAGE CONDITIONS**

Chlorhexidine Acetate with Cetrimide Antiseptic Solutions are supplied in 3 strengths. Each strength has 3 sizes (see Table 1).

**Table 1**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pack Size</th>
<th>Product Code</th>
<th>ARTG Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine Acetate 0.015% Cetrimide 0.15%</td>
<td>100 mL</td>
<td>AHF7971</td>
<td>19458</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.015% Cetrimide 0.15%</td>
<td>500 mL</td>
<td>AHF7970</td>
<td>19458</td>
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<tr>
<td>Chlorhexidine Acetate 0.015% Cetrimide 0.15%</td>
<td>1000 mL</td>
<td>AHF7969</td>
<td>19458</td>
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<td>Chlorhexidine Acetate 0.05% Cetrimide 0.5%</td>
<td>100 mL</td>
<td>AHF7979</td>
<td>19460</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.05% Cetrimide 0.5%</td>
<td>500 mL</td>
<td>AHF7988</td>
<td>19460</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.05% Cetrimide 0.5%</td>
<td>1000 mL</td>
<td>AHF7987</td>
<td>19460</td>
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<tr>
<td>Chlorhexidine Acetate 0.10% Cetrimide 1.0%</td>
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<td>AHF7973</td>
<td>19462</td>
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<tr>
<td>Chlorhexidine Acetate 0.10% Cetrimide 1.0%</td>
<td>500 mL</td>
<td>AHF7972</td>
<td>19462</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.10% Cetrimide 1.0%</td>
<td>1000 mL</td>
<td>AHF7968</td>
<td>19462</td>
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</tbody>
</table>
**Storage Conditions**
Chlorhexidine Acetate with Cetrimide Antiseptic Solution should be stored below 30°C. Do not heat in excess of 80°C. Protect from light.

**NAME AND ADDRESS OF THE SPONSOR**
Baxter Healthcare Pty. Ltd.,
1 Baxter Drive
Old Toongabbie, NSW 2146.

**POISON SCHEDULE OF THE MEDICINE:** Not scheduled.

**DATE OF FIRST INCLUSION ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS:** 30 September 1991

**DATE OF MOST RECENT AMENDMENT:** 19 February 2015