CHLORHEXIDINE ACETATE ANTISEPTIC SOLUTION

NAME OF THE MEDICINE

Proprietary name: Baxter Chlorhexidine Antiseptic Solution
Non-proprietary name: Chlorhexidine Antiseptic 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
Molecular Formula: C₂₂H₃OCl₂N₁₀₂C₂H₄O₂.

DESCRIPTION

Chlorhexidine Acetate (0.02%, 0.05%, 0.1% and 0.5%) Antiseptic solutions are clear, slightly blue sterile solutions.

Active Ingredients: Chlorhexidine Acetate BP 0.02% w/v, 0.05% w/v, 0.1% w/v and 0.5% w/v.
Inactive Ingredients: Cetrimide 0.1% w/v (in Chlorhexidine Acetate 0.5% solution), Methyl blue, glacial acetic acid and Water for Injections BP.

This solution is used as a general antiseptic, and is also recommended for disinfection of respirators. The solution is hypotonic and is haemolytic. It is supplied in 4 strengths. Each strength is supplied in 3 sizes (see Table 1).

PHARMACOLOGY

Chlorhexidine Acetate Antiseptic solution is used as a topical solution; it must not be administered intravenously.

INDICATIONS

Chlorhexidine Acetate Antiseptic solution is used as a general antiseptic. It is used for the cleaning and disinfecting of wounds and the antiseptic treatment of burns.

CONTRAINDICATIONS

Known hypersensitivity to chlorhexidine or methylene blue. Chlorhexidine Acetate 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

General

- Chlorhexidine Acetate Antiseptic solution should not be used intravenously or taken orally. Do not swallow. If swallowed seek urgent medical attention.

- It should not be used if you have a history of allergy to any of the ingredients of Chlorhexidine Acetate Antiseptic Solution.

- 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 tamper proof seal is intact.

Hypersensitivity Reactions

- Hypersensitivity reactions including anaphylactic/anaphylactoid reactions have been reported with chlorhexidine. Fatal anaphylactic reactions have been reported with other products containing chlorhexidine.

- If any signs or symptoms of a suspected hypersensitivity reaction develop, immediately stop use the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Chemical Burns in Neonates

- 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.

Preoperative Skin preparation

- Chlorhexidine should not be used in preoperative skin preparations for face or head.

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.

The use of chlorhexidine solutions has been associated with skin reactions such as chemical burns in neonates.

**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 cardiac arrest, circulatory collapse, hypotension, bronchospasm, rash, erythema, tachycardia, urticaria 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 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. Dosage and duration of
administration are to be individualized and depend upon the indication for use, the patient’s ages, weight, clinical condition, concomitant treatment and on patient’s clinical response to treatment.

Not for intravenous or oral route of administration.

Product should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. Do not use unless the solution is clear and the seal is intact.

**Directions for use**

The area where Chlorhexidine Acetate 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. Allow to dry for 3 minutes

Discard within 24 hours of opening.

**To open**

Hold Steripour® bottle and twist lid to open, breaking the tamper proof seal.

**OVERDOSAGE**

Chlorhexidine is poorly absorbed by the gastrointestinal tract. If ingested, advice concerning treatment should be sought immediately from a doctor or contact the Poisons Information Centre on 131126.

**PRESENTATION AND STORAGE CONDITIONS**

Chlorhexidine Acetate Antiseptic solution is supplied in 4 strengths. Each strength has 3 sizes (see Table 1). It is packaged in plastic pour bottles, sealed with a tamper proof lid.

**Table 1**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pack size</th>
<th>Product Code</th>
<th>ARTG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine Acetate 0.02%</td>
<td>100mL</td>
<td>AHF7976</td>
<td>19459</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.02%</td>
<td>500mL</td>
<td>AHF7980</td>
<td>19459</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.02%</td>
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<td>AHF7981</td>
<td>19459</td>
</tr>
<tr>
<td>Chlorhexidine Acetate 0.05%</td>
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<td>AHF7977</td>
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<td>500mL</td>
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<td>19461</td>
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<td>AHF7985</td>
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<tr>
<td>Chlorhexidine Acetate 0.1%</td>
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<td>AHF7986</td>
<td>19463</td>
</tr>
</tbody>
</table>
Storage Conditions

Chlorhexidine Acetate 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: 13 September 2016