

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Acetate 0.015% w/v and Cetrимide 0.15% w/v, Irrigation Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Acetate	BP	0.15g/1000ml
Cetrimide	Ph.Eur	1.5g/1000ml

3. PHARMACEUTICAL FORM

Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% w/v, Irrigation Solution is a clear, yellow, sterile, aqueous solution for general topical use.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% w/v, Irrigation Solution is for general topical use, combining antibacterial activity against a wide range of vegetative gram-positive and gram-negative bacteria with useful cleansing properties.

The solution is recommended for the cleansing and disinfection of wounds and the antiseptic treatment of burns.

Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% w/v, Irrigation Solution is recommended for swabbing in obstetrics, gynaecology and urology.

4.2 Posology and method of administration

Dosage

Dosage and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, and concomitant treatment, and on patient's clinical response to treatment (See Section 4.4 Chemical Burns in Neonates and Preoperative Skin Preparation).

Administration

Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% w/v, Irrigation Solution is for general topical use. This solution is used undiluted for topical application only. Not for intravenous or oral route of administration.

4.3 Contraindications

This solution should not be used in the eye, intravenously, orally, in the auditory canal (especially in perforated eardrums), or near meninges brain or spinal cord (See Section 4.4 Special Warnings and Precautions for Use).

In patients with a known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

The solution is not for intravenous administration. The solution shall not be taken orally.

Accidental ingestion should be treated with a stomach lavage consisting of milk, egg white, gelatin or mild soap.

Idiosyncratic reactions to Chlorhexidine Acetate BP and Cetrimide Ph.Eur. have been reported.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylactic/anaphylactoid reactions, have been reported with chlorhexidine. Fatal anaphylactic reactions have been reported with other products containing chlorhexidine (See Section 4.8 Adverse Reactions).

If any signs or symptoms of a suspected hypersensitivity reaction develop, immediately stop use. 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. 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

Caution should be exercised when chlorhexidine is used in preoperative skin preparations for face or head (See Section 4.3 Contraindications).

Chlorhexidine must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that chlorhexidine does not migrate beyond its intended application site into the eyes. Particular care should be taken in anesthetized patients, who are unable to immediately report ocular exposure. If chlorhexidine comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

Use in Pediatric Patients

The use of chlorhexidine solutions has been associated with skin reactions such as chemical burns in neonates (See Section 4.4 Warnings – Chemical Burns in Neonates). This product should only be used in specialist units familiar with the appropriate selection of patients.

4.5 Interaction with other medicinal products and other forms of interaction

The action of chlorhexidine is reduced by alkaline pH, the presence of organic matter, anionic detergents and tannins. The effect of chlorhexidine will be inactivated on contact with soap or blood.

4.6 Fertility, pregnancy and lactation

Physicians should carefully consider the potential risks and benefit for each specific patient before prescribing chlorhexidine.

Chlorhexidine has been used in pregnant women and no harmful effects have been reported.

There are no adequate data to support the use of chlorhexidine in lactating women.

Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% w/v, Irrigation Solution is recommended for swabbing in obstetrics and gynaecology.

4.7 Effects on ability to drive and use machines

Chlorhexidine Acetate and Cetrimide has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Hypersensitivity reactions including anaphylactic/anaphylactoid reactions manifested by cardiac arrest, shock, circulatory collapse, hypotension, bronchospasm, tachycardia, rash, erythema and urticaria

Skin and subcutaneous tissue disorders:

Rash

Other Adverse Reactions(Class Reactions)

The adverse events reported and/or observed with other chlorhexidine products include:

Fatal anaphylactic reactions

Chemical burns in neonates (See Section 4.4 Special Warnings and Precautions for Use).

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, generalised erythema, urticaria and loss of consciousness. Other effects that have been noted include pain, haematuria and/or increased urge to urinate.

Idiosyncratic reactions to chlorhexidine acetate have been reported and are well documented.

Eye Disorder: Frequency not known: Corneal erosion, corneal epithelium defect/ injury corneal, visual impairment*

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see Section 4.4 Special Warnings and Precautions for Use).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Overdose of chlorhexidine may constitute a medical emergency. In case of accidental overdose seek immediate medical attention

Not applicable if the solution is used appropriately.

Chlorhexidine is poorly absorbed by the gastro-intestinal. In case of accidental oral intake, perform gastric lavage and/or wash out the stomach with milk, egg white, gelatine or a mild soap.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Therapeutic Group: D08A – Antiseptics and Disinfectants

These solutions are intended for use as an external irrigating solution and as an effective disinfectant against Gram-positive and Gram negative bacteria. Chlorhexidine is more effective against Gram-positive bacteria than Gram-negative bacteria, including some Pseudomonas and Proteus species that may be less sensitive.

5.2. Pharmacokinetic properties

Given the method for use of these solutions, absorption through the skin is minimal, no significant levels being found in blood.

5.3. Preclinical safety data

Given its topical application, the potential toxicity of these products is very low.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sunset yellow E110 8.0 mg per litre

Acetic acid EP QS

Water for Injections EP TO 1.0L

6.2 Incompatibilities

Prolonged immersion of rubber appliances in this solution should be avoided.

Additives may be incompatible with chlorhexidine.

Chlorhexidine must not be mixed with soaps or other anionic materials.

6.3. Shelf life

The shelf life is 24 months providing the unit has not been opened.

6.4. Special precautions for storage

Storage temperature should not exceed 25°C.

Protect solution from light.

6.5. Nature and contents of container

The product is supplied in high density polyethylene bottles or sachets manufactured from a nylon/polypropylene laminate. The solution in Pour Bottles is supplied in 100ml, 250ml, 500ml and 1000ml volumes and the solution in sachets is 100ml and 25ml volumes.

6.6 Special precautions for disposal

Do not use unless solution is clear and the container is undamaged.

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.

7. MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,
Caxton Way,
Thetford,
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8. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0096

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/10/2024

10. DATE OF REVISION OF THE TEXT

05/11/2024