SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Acetate BP 0.05% w/v for Irrigation.

2. Qualitative and Quantitative Composition

2.1. Active Ingredients

Chlorhexidine Acetate	BP

2.2. Quantitative Composition

Chlorhexidine Acetate	0.495g/1000ml

3. Pharmaceutical Form

Sterile, non-pyrogenic irrigating solution for administration to human beings.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine Acetate BP is a disinfectant which is effective against a wide range of vegetative gram-positive and gram-negative bacteria.

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 BP 0.02% w/v for Irrigation is recommended for

general topical use when antibacterial irrigation is indicated, including wound and burn irrigation and for the disinfection of respirators.

Not for intravenous or oral route of administration.

4.3 Contraindications

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)."

Do not use in the eye, auditory canal (especially in perforated eardrums), or near meninges, brain or spinal cord (See Section 4.4 Special Warnings and Precautions for Use).

4.4 Special warnings and precautions for use

This product should only be used in specialist units familiar with the appropriate selection of patients.

This solution is not to be taken orally.

This solution is not for intravenous administration. Accidental ingestion should be treated with a stomach lavage consisting of milk, egg white, gelatine or mild soap.

Idiosyncratic reactions to Chlorhexidine Acetate BP 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).

4.5 Interaction with other medicinal products and other forms of interaction

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

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.

4.7 Effects on ability to drive and use machines

Chlorhexidine acetate 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)

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2. Pharmacokinetic Properties

Not applicable.

5.3. Preclinical Safety Data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections EP To 1000ml
Acetic Acid (pH adjustment) QS

6.2 Incompatibilities

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 direct sunlight.

6.5. Nature and Contents of Container

100ml, 500ml and 1000ml pour bottles and form-fill-seal containers.

6.6 Special precautions for disposal

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 Limited.,
Caxton Way,
Thetford,
Norfolk
IP24 3SE

8. Marketing Authorisation Number

PL 0116/0141

9. Date of First Authorisation/Renewal of Authorisation

09.11.84 / 29.02.96

10 DATE OF REVISION OF THE TEXT

05/11/2024