Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Acetate BP 0.05% w/v Irrigation solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One litre contains:
Chlorhexidine Acetate 0.5g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Irrigation solution.

Clear colourless, sterile, aqueous irrigation solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a disinfectant for topical irrigation of wounds and burns.
For disinfection of respirators.

4.2 Posology and method of administration

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).

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.

Method of administration:

Topical Irrigation

4.3 Contraindications

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).

Do not use in patients with known hypersensitivity to chlorhexidine.

Not for us in abdominal cavities, unless under supervision of a specialist.

4.4 Special warnings and precautions for use

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.

Hypersensitivity reactions have been reported on contact with chlorhexidine.

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

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

Do not use unless solution is clear, free of particles and container intact

Use in Paediatric Patients: 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).

4.5 Interaction with other medicinal products and other forms of interactions

The activity of chlorhexidine is not significantly affected by blood or other organic materials. However, its activity is pH-dependent (5.5-7.0) and is reduced or neutralized in the presence of non-ionic surfactants, inorganic anions (e.g., phosphate, nitrate, chloride, and other substances that are present in hard tap water and in many pharmaceutical preparations), and organic anions such as natural soaps.

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 benefits for each specific patient before prescribing Chlorhexidine Acetate 0.05% w/v. There are no adequate data to support the use of Chlorhexidine Acetate 0.05% w/v in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

There is no information of the effects of chlorhexidine on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported in post marketing experience, listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.

Immune System Disorders:
Hypersensitivity reactions including anaphylactic/anaphylactoid reactions (which might be fatal) manifested by cardiac arrest, shock, circulatory collapse, hypotension, bronchospasm, tachycardia, rash, erythema and urticaria.

Skin And Subcutaneous Tissue Disorders:

Rash

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

Chemical burns in neonates (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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Websitw; www.hpra.ie e-mail: medsafety@hpra.ie

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

Pharmacotherapeutic group: D08AC02

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Acetic Acid (for pH adjustment)

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Additives may be incompatible with chlorhexidine.

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

6.3 Shelf life

Unopened: 2 years.

Opened: For single-use only.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container in order to protect from light.

6.5 Nature and contents of container

The product will be supplied in High Density Polyethylene Single-Use containers of 1000ml.

6.6 Special precautions for disposal and other handling

Do not use unless solution is clear and the container is undamaged.
Discard unused portion.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Baxter Holding B.V.
Kobaltweg 49
3542CE Utrecht
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA2299/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

December 2018