Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine acetate 0.015% w/v and Cetrimide 0.15% w/v Irrigation solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One litre contains:
Chlorhexidine Acetate 0.150 g
Cetrimide 1.5 g

Excipients with known effect: Sunset Yellow (E110) 8mg/L

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Irrigation solution
A clear, yellow, sterile, nonpyrogenic, aqueous irrigation solution.
pH 5.0-6.5

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a disinfectant for topical antibacterial irrigation of wounds and burns, and some body cavities such as the bladder. For disinfection of respirators.

4.2 Posology and method of administration

Posology
The dosage is dependant upon the age, weight and clinical condition of the patient.

Method of administration
Topical irrigation.

4.3 Contraindications

Do not use in patients with known hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
This product should not be used in the eye, intravenously, orally, in the auditory canal, or near meninges, brain or spinal cord.

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 acetate or Cetrimide.

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

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and 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 Acetate 0.015% w/v and Cetrimide 0.15% w/v Irrigation Solution, care must be taken to ensure no excess product is present prior to application of the dressing.

Caution should be exercised when chlorhexidine is used in preoperative skin preparations for face or head

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

Sunset yellow (E110) may cause allergic reaction.

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

Refer to sections 4.8 and 4.9 for information on accidental intake.

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 sub-.stances that are present in hard tap

water and in many pharmaceutical preparations), and organic anions such as natural soaps.

4.6 Fertility, pregnancy and lactation

Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15%. There are no adequate data to support the use of Chlorhexidine Acetate 0.015% w/v and Cetrimide 0.15% in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

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

Other Adverse Reactions:
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)

The following reactions have been noted when Chlorhexidine containing irrigation solutions have been used intravesically, intravaginally or topically on traumatised skin: Hypotension, paraesthesia, dyspnea, tachycardia, cold sweat, generalised erythema, urticaria and loss of consciousness.
Chemical burns in neonates (frequency unknown).

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. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

Chlorhexidine is poorly absorbed by the gastro-intestinal tract. In case of accidental oral intake, proceed to a gastric lavage and/or wash the stomach with milk, eggs, gelatin or a mild soap.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: D08AC52 chlorhexidine, combinations.

Not applicable

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunset Yellow (E110)
Acetic Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf life

Unopened: 2 years
Once opened: Use immediately. Discard any unused product.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

High density polyethylene container. The product is supplied in a 500ml and 1000ml volumes.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Do not use unless solution is clear and the container is undamaged.Discard any unused portion.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2299/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

December 2018