SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Irrigaton Solution

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains <STRENGTH> of chlorhexidine acetate and <STRENGTH> of cetrimide.

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Irrigation Solution

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   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.

* 1. 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.

* 1. 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).

* 1. 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

Chlorhexidine Acetate and Cetrimide contains chlorhexidine, which is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock, which can be fatal. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. This product should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

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 and Pediatric Patients

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).

* 1. 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.

* 1. 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.

* 1. Effects on ability to drive and use machines

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

* 1. Undesirable effects

Immune system disorders (frequency not known):

Hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions (see sections 4.3 and 4.4) manifested by cardiac arrest, circulatory collapse, hypotension, bronchospasm, tachycardia, rash, erythema and urticaria

Skin and subcutaneous tissue disorders (frequency not known):

Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Other Adverse 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.

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 Health Product Vigilance Center; HPVC

* 1. 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.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and Disinfectants, ATC code: D08A

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.

* 1. Pharmacokinetic properties

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

* 1. Preclinical safety data

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

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. 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.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>