Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterets Unisept 0.05% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.05 % w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.
A clear, pink sterile cutaneous solution contained within a colourless, plastic sachet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Chlorhexidine gluconate is a potent antibacterial agent for general antiseptic purposes. It is bactericidal to a broad spectrum of organisms. Sterets Unisept is recommended for use in obstetrics and for swabbing burns and wounds.

4.2 Posology and method of administration

For cutaneous application.

There is no distinction between adults, children or the elderly. Sterets Unisept should be used without further dilution for topical administration only.

4.3 Contraindications

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).

Sterets Unisept should not come into contact with brain, meninges or middle ear.

4.4 Special warnings and precautions for use

Sterets Unisept contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Sterets Unisept 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).

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 Sterets Unisept, care must be taken to ensure no excess product is present prior to application of the dressing.

1. When used in aseptic procedures, the outside of the sachet should be disinfected before opening.
2. Any surplus should be discarded immediately after use.
3. For external use only. NOT for injection.

4. Do not use within body cavities.
5. Contact with the eyes should be avoided.

4.5 Interaction with other medicinal products and other forms of interactions

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with Sterets Unisept solution.

Sterets Unisept is incompatible with anionic agents.

4.6 Fertility, pregnancy and lactation

Although there are no adverse reports for this product in pregnant and lactating mothers, as with all medicines, care should be exercised when administering the product to pregnant or lactating women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very Common (≥1/10); Common (≥1/100, <1/10); Uncommon (≥1/1,000, <1/100); Rare (≥1/10,000, <1/1,000); Very rare (<1/10,000); not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune system disorders:
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Injury, poisoning and procedural complications:
Frequency not known: Chemical burns in neonates

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

Accidental ingestion: Gastric lavage should be carried out with milk, egg white, gelatine or mild soap.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants, ATC code: D08AC02

Chlorhexidine is a disinfectant which is effective against a wide range of vegetative Gram-positive and Gram-negative bacteria; it is more effective against Gram-positive than Gram-negative bacteria, some species of *Pseudomonas* and *Proteus* being less susceptible. The wide range of organisms against which chlorhexidine is active explains the rationale for presenting it in a solution for swabbing wounds and burns and in obstetrics.

5.2 Pharmacokinetic properties

The BP 1993 contains a monograph for chlorhexidine gluconate.
The pharmacokinetics of the compounds when applied to the skin as a topical antiseptic are well described in the literature.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Nonoxinol 9
Carmoisine Red (E122)
Sodium Hydroxide (for pH-adjustment)

6.2 Incompatibilities

Sterets Unisept is incompatible with anionic agents.

6.3 Shelf life

18 months.
Once opened use immediately and discard any unused portion.

6.4 Special precautions for storage

Do not store above 25°C.

Store sachets in outer container (plastic pouch)

6.5 Nature and contents of container

25 ml or 100 ml in polyamide / polypropylene copolymer laminate sachets in a polythene / polyamide pouch.

Pack sizes: Pouch containing 25 x 25 ml sachets or 10 x 100 ml sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Medlock Medical Ltd
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Medlock Street
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OL1 3HS
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8 MARKETING AUTHORISATION NUMBER

PA1175/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th May 1988

Date of last renewal: 30th May 2008

10 DATE OF REVISION OF THE TEXT

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