STERETS UNISEPT

PHYSICIAN'S LEAFLET

1. NAME OF THE MEDICINAL PRODUCT

Sterets Unisept.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate Solution 20% w/v 0.05% w/v.

3. PHARMACEUTICAL FORM

Sterile Aqueous Solution.

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

Cutaneous.

There is no distinction between adults, the elderly and children. 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 the 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.

For external use only. Not for injection. When Sterets Unisept is used in aseptic procedures, the outside of the sachet should be disinfected before opening. Discard any surplus immediately after use. Contact with eyes should be avoided. Do not use within body cavities.

4.5 Interaction with other medicinal products and other forms of interaction

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

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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

Treatment
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 (British Pharmacopoeia) 1993 contains a monograph for Chlorhexidine Gluconate Solution 20% w/v. The pharmacokinetics of the compound when applied to the skin as a topical antiseptic are well understood and described in the literature.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nonoxinol 9; sodium hydroxide; Carmoisine Red (E122); purified water.

6.2 Incompatibilities

Sterets Unisept is incompatible with anionic agents.

6.3 Shelf life

24 months unopened.
Shelf life after first opening: Once opened use immediately and discard any unused portion.

6.4 Special precautions for storage

Do not store above 25ºC. Store sachets in outer container (plastic pouch).

6.5 Nature and contents of container

Nylon-ethylene-propylene copolymer laminate sachets containing either 25 ml or 100 ml of product

overwrapped in heat sealed polythene/nylon and / or polythene/polyester pouches.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MANUFACTURER

Medlock Medical Ltd, Tubiton House, Medlock Street, Oldham, OL1 3HS.

8. REGISTRATION NUMBER(S)

156-34-34404-00

9. LICENCE HOLDER

RAZ pharmaceutics LTD., 6 Hamatechet St., Kadima.

The content of this leaflet was approved by the Ministry of Health in June 2016 and updated according to the guidelines of the Ministry of Health in July 2018.