STERETS TISEPT SACHETS
PHYSICIAN'S LEAFLET

1. NAME OF THE MEDICINAL PRODUCT

Sterets Tisept Sachets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.015% w/v
(incorporated as 20% w/v Chlorhexidine gluconate Solution)

Cetrimide 0.15% w/v

3. PHARMACEUTICAL FORM

Cutaneous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A broad spectrum antiseptic with detergent properties for swabbing in obstetrics and during dressing changes. For disinfecting and cleansing traumatic and surgical wounds and burns.

4.2 Posology and method of administration

Cutaneous.

Use 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 Tisept should not come into contact with the brain, eyes, meninges or middle ear.

4.4 Special warnings and precautions for use

Sterets Tisept Sachets 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 Tisept Sachets 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 Tisept Sachets, 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 used in aseptic procedures, the outside of the sachet should be

disinfected before opening. Discard any surplus immediately after use. 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 Tisept solution.

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

In addition, cetrimide has been reported to cause dry skin and in rare cases chemical burn after repeated application.

Reporting side effects:
Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il

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: D08AC52

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. Cetrimide is a quaternary ammonium disinfectant with properties and uses typical of cationic surfactants. It is used in Sterets Tisept antiseptic for its surfactant and bactericidal properties.

5.2 Pharmacokinetic properties

The British Pharmacopea 1993 contains monographs for both Chlorhexidine Gluconate solution 20% w/v and Cetrimide. The pharmacokinetics of the compounds when applied to the skin are well described in the literature.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, Sunset Yellow E110, Sodium hydroxide (for pH-adjustment).

6.2 Incompatibilities

Sterets Tisept is incompatible with anionic agents.

6.3 Shelf life

18 months unopened.

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

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.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MANUFACTURER

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

8. REGISTRATION NUMBER(S):

156-35-34405-00

9. LICENCE HOLDER

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

10. The format of this leaflet was determined by the Ministry of health (MOH) and its content was checked and approved by the MOH in June 2016, and was updated according to the Ministry of Health's instructions in December 2019.

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