SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sterets Tisept Sachets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate Solution 20% w/v 0.015%w/v
Cetrimide 0.15%w/v 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 Interactions 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 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 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:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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**

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 BP 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 **Pre clinical safety data**

Not applicable.

6. **PHARMACEUTICAL PARTICULARS**

6.1. **List of excipients**

Purified Water
Sunset Yellow E110
Sodium Hydroxide.

6.2. **Incompatibilities**

Sterets Tisept is incompatible with anionic agents.

6.3. **Shelf life**

36 months unopened.

6.4 **Special precautions for storage**

Do not store above 25°C. Store in the original package.

6.5 **Nature and contents of container**

Nylon/ethylene propylene copolymer laminate sachets overwrapped in heat sealed polythene/nylon and/or polythene/polyester pouches.

Pack sizes; 25ml and 100ml.

6.6 **Special precautions for disposal**
7. MARKETING AUTHORISATION HOLDER

Medlock Medical Ltd
Tubiton House
Oldham
OL1 3HS
England.

8. MARKETING AUTHORISATION NUMBER

PL 21248/0035

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION


10. DATE OF REVISION OF THE TEXT

10/12/2014