

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterets Tisept Sachets 0.015% w/v and 0.15% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.015 % w/v

Cetrimide 0.15 % w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution

A clear, yellow, sterile 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

For topical application.

Cleanse affected area or involved skin with undiluted preparation.

4.3 Contraindications

1. 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).
2. Use in contact with brain, 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.

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 Tisept Sachets 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 ($\geq 1/10$); Common ($\geq 1/100$, $< 1/10$); Uncommon ($\geq 1/1,000$, $< 1/100$); Rare ($\geq 1/10,000$, $< 1/1,000$); 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: 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: 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 Sachets antiseptic for its surfactant and bactericidal properties.

5.2 Pharmacokinetic properties

The BP 1993 contains monographs for both Chlorhexidine Gluconate and Cetrimide. The pharmacokinetics of the compounds when applied to the skin are well described in the literature.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Sunset Yellow (E110)
Sodium Hydroxide (for pH adjustment)

6.2 Incompatibilities

Sterets Tisept Sachets are 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
Tubiton House
Medlock Street
Oldham
OL1 3HS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1175/014/001

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

23 August 2019

CRN00919G

Page 3 of 4

