

Sterets® Tisept Sachets

Package leaflet: Information for the patient

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

Chlorhexidine gluconate / Cetrimide

Read all of this leaflet carefully before you are administered this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or nurse if you need more information or advice.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sterets Tisept Sachets is and what it is used for
2. What you need to know before Sterets Tisept Sachets is used
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1. What Sterets Tisept Sachets is and what it is used for

Sterets Tisept is a sterile, yellow, cutaneous solution containing Chlorhexidine gluconate and Cetrimide which have antiseptic properties (that is, it kills germs).

Sterets Tisept Sachets are used to help prevent infection from occurring during and after childbirth and also in wounds and burns.

2. What you need to know before Sterets Tisept Sachets is used

Do not use Sterets Tisept Sachets:

- if you are allergic to Chlorhexidine gluconate, Cetrimide or to any of the other ingredients of this medicine (listed in section 6). If you are not sure if this applies to you, talk to your doctor or nurse before this medicine is used.
- if the product could come into contact with the brain, meninges (the membranes surrounding the brain and spinal cord) or the inside of the ear.
- inside the body's internal spaces.

Warnings and precautions

Talk to your doctor or nurse before Sterets Tisept Sachets is used.

- Avoid contact with the eyes and ears.
- Common bleaches (which contain hypochlorites) may cause brown stains to develop in fabrics which have previously been in contact with Sterets Tisept solution.
- The product's action may be reduced if used with soap or detergents.

Children

Use with care in newborn babies, especially those born prematurely. Sterets Tisept Sachets may cause chemical skin burns.

Other medicines and Sterets Tisept Sachets

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before this medicine is used.

3. How Sterets Tisept Sachets will be used

For external use on the skin only.

Not for injection.

When used in a sterile procedure, the outside of the sachet should be disinfected with a 70% isopropyl alcohol solution before opening.

Any surplus product should be immediately discarded after use.

Undiluted Sterets Tisept Solution will be applied to the affected area of skin.

IF YOU ACCIDENTALLY SWALLOW ANY STERETS TISEPT SOLUTION, SEEK MEDICAL ADVICE IMMEDIATELY, TAKING THIS LEAFLET WITH YOU.

If you have any further questions on the use of this medicine, ask a doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur; it is not known how often these happen but available data suggests these are very rare (probably affect fewer than 1 in every 10,000 people).

- Serious allergic reactions which can cause breathing difficulties, weakness, collapse and death, and can sometimes be preceded by swelling (in particular lip/tongue and facial swelling), or rash.

At the first sign of any of these reactions, tell your doctor or nurse and application of Sterets Tisept Sachets should be stopped immediately.

Other possible side effects, for which it is not known how often they occur, are: allergic skin disorders such as dermatitis (inflammation of the skin), pruritus (itch), erythema (redness of the skin), eczema, rash, urticaria (hives), skin irritation and blisters.

Dry skin and in rare cases chemical burns have been reported after repeated use.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sterets Tisept Sachets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is printed on the plastic sachets.

The expiry date refers to the last day of that month.

Do not store the product above 25°C.

Store the sachets in the outer container (plastic pouch).

Do not use Sterets Tisept Sachets if you notice any damage to, or leakage from, the plastic pouches. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sterets Tisept Sachets contains

- The active substances are Chlorhexidine gluconate 0.015% w/v and 0.15% w/v Cetrimide.
- The other ingredients are Purified water, Sunset yellow (E110) and Sodium hydroxide.

What Sterets Tisept Sachets looks like and contents of the pack

Sterets Tisept is a clear yellow cutaneous solution presented in plastic laminate sachets containing either 25ml or 100ml of the liquid. These sachets are packed together in an outer plastic pouch.

Marketing Authorisation Holder And Manufacturer

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