

This medicine is dispensed without a doctor's prescription.

## **Sterets® Unisept Cutaneous Solution**

**Chlorhexidine gluconate 0.05% w/v**

For the list of inactive ingredients see section 6.

**Carefully read the entire leaflet before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine was prescribed to you. Do not pass it on to others. It may harm them, even if it seems that they have a similar medical condition.

Use the medicine correctly. Ask your doctor if symptoms worsen or do not improve.

The medicine is intended for adults and children.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Sterets Unisept sachets are used to help prevent infection from occurring during and after childbirth, and also in wounds and burns.

**Therapeutic group:** Antiseptic solution.

### **2. BEFORE USING THE MEDICINE**

**Do not use this medicine:**

- If you are allergic to Chlorhexidine gluconate 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 using this medicine.
- 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.
- In the internal cavities of the body.

#### **Special warnings regarding the use of this medicine**

- Talk to your doctor or nurse before using Sterets Unisept sachets.
- Avoid contact with the eyes and ears.
- Household bleaches (which contain hypochlorites) may cause brown stains to appear on fabrics that have had contact with Sterets Unisept solution.
- The product's effectiveness may be impaired if used with soap or detergents.

#### **Children**

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

**Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutritional supplements.**

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or nurse for advice before using this medicine.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Check with your doctor or pharmacist if you are not sure.

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 70% isopropyl alcohol before opening.

Any remaining solution should be discarded after use.

Apply the undiluted solution to the affected skin area.

**If you accidentally swallow any Sterets Unisept solution, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you.**

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

#### **4. SIDE EFFECTS:**

As with any medicine, the use of Sterets Unisept sachets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**The following side effects may occur; it is not known how often they occur 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. Sometimes a serious allergic reaction may begin with 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 stop using Sterets Unisept immediately.**

**Additional side effects, whose frequency is unknown, 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.

#### **Reporting side effects:**

You can report side effects to the Ministry of Health by clicking on the link "report side effects of drug treatment" on the homepage of the Ministry of Health ([www.health.gov.il](http://www.health.gov.il)) which refers to an online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and any other medicine must be kept in a secure place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed by the doctor.
- Do not use this medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at temperatures exceeding 25°C.
- Store the sachets in their original outer container (plastic pouch).
- Do not use this medicine if you notice any damage to, or leakage from, the plastic pouches.
- Do not throw away the medicine via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Purified water, Nonoxinol 9, Carmoisine Red food coloring (E122) and Sodium hydroxide.

#### **What the medicine looks like and contents of the pack**

Sterets Unisept is a clear pink cutaneous solution sold in plastic laminate sachets containing either 25 ml or 100 ml of solution. These sachets are packed together in an outer plastic pouch.

**Drug registration number: 156-34-34404-00**

**This leaflet was checked and approved by the Ministry of Health in: June 2016**

#### **Manufacturer:**

Medlock Medical Ltd., Tubiton House, Medlock Street, Oldham, OL13HS, United Kingdom

#### **License holder:**

Raz Pharmaceuticals Ltd., 6 Hamatechet St., Kadima, Israel