

## **PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

**SAVIOR®**

**Cream**

### **Composition**

Cetrimide 0.5% w/w Chlorhexidine hydrochloride 0.1% w/w

For information about inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult with the pharmacist if you require further information. Refer to the doctor if symptoms of the illness worsen or do not improve.

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

First aid antiseptic for external use in minor injuries, wounds and burns.

#### **Therapeutic group:**

Antiseptics.

Chlorhexidine hydrochloride is an antiseptic with a broad spectrum of activity against microorganisms including bacteria, fungi and viruses.

Cetrimide has antiseptic characteristics.

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

#### **Do not use the medicine if:**

you have a known sensitivity to any of the ingredients of the medicine, especially to chlorhexidine hydrochloride, which may cause an allergic reaction. The medicine contains cetostearyl alcohol, which could cause a local skin reaction (e.g., contact dermatitis).

#### **Special warnings regarding use of Savior Cream:**

- For external use only. Do not swallow.
- You may experience discomfort if you have sensitive skin.
- Stop using the medicine if you experience irritation or other undesirable effects.
- Avoid contact with the brain, meninges (the membranes surrounding the brain and spinal cord) and middle ear.
- Do not use in the eye area since contact with the eye may lead to damaged vision. If the medicine comes into contact with the eye, immediately rinse thoroughly with water. In any case of irritation, eye redness or pain or vision disturbance, refer to a doctor immediately.

Serious cases of persistent corneal damage (injury to the surface of the eye), potentially requiring a corneal transplant, have been reported following accidental ocular exposure to similar medicines during surgical procedures, in patients under general anesthesia.

- Avoid using soap and other anionic agents together with Savior Cream.

#### **Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

#### **Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before use.

#### **Pregnancy**

There are no data regarding use during pregnancy. The potential risk for humans is unknown, but it is likely very low since chlorhexidine hydrochloride and cetrimide are poorly absorbed when topically applied.

#### **Breastfeeding**

It is not known whether chlorhexidine hydrochloride and cetrimide are excreted into breast milk.

There are no data regarding use when breastfeeding. However, it is unlikely that the medicine is excreted into breast milk, since the absorption is low.

After using Savior Cream in the chest area, it is recommended to wash the area thoroughly with water before breastfeeding.

#### **Fertility**

There are no data regarding an effect on fertility.

#### **Important information about some of the ingredients of the medicine:**

The medicine contains cetostearyl alcohol, which could cause a local allergic reaction in the skin (e.g., contact dermatitis).

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

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

#### **Directions for use:**

- For external use only. Do not swallow!
- Wash hands thoroughly before and after use.
- Clean the affected area with clean water and dry.
- Gently spread the cream in a thin layer on the affected area with your fingers or a gauze pad.
- For cuts and small injuries, protect the area with a bandaid or dressing.
- Burns: should preferably be left uncovered.
- Repeat the process as needed. Do not use in the eye area. In case of contact with the eyes, rinse them well with water.

If there is no improvement in your condition within several days, refer to a doctor.

**If you took an overdose** or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

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

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

### **4. SIDE EFFECTS**

As with any medicine, use of Savior Cream 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.

**Stop using the medicine and refer to the doctor immediately if:**

You experience any of the following rare allergic reactions: breathing difficulties, swelling of the face, tongue or throat, dizziness.

#### **Other possible side effects, of unknown frequency:**

- Allergic skin reactions, such as dermatitis (an inflammation of the skin), itching, erythema (skin redness), eczema, rash, urticaria (hives), irritation and skin blisters.
- Corneal damage (injury to the surface of the eye), permanent damage to the eyes, including permanent vision impairment (following accidental ocular exposure during a surgical procedure in the head area in patients under general anesthesia).

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

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

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions: Store this medicine below 25°C.**
- **Savior Cream can be used for up to 12 months after first opening the tube, but not later than the expiry date of the medicine.**

### **6. FURTHER INFORMATION**

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

Purified water, Cetostearyl alcohol, Mineral oil (paraffin oil).

**What the medicine looks like and contents of the package:**

An aluminium tube containing a white, smooth homogeneous cream, free of lumps.

The tube contains 10 grams.

**Name of Manufacturer and License Holder and its Address:**

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

**Revised in September 2024.**

**Registration number of the medicine in the National Drug Registry of the Ministry of Health: 126.25.21373**