SUMMARY OF PRODUCT CHARACTERISTICS

Savior®
Cream

1. NAME OF THE MEDICINAL PRODUCT

Savior® Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 0.5% w/w
Chlorhexidine Dihydrochloride 0.1% w/w
1 gram of Savior cream contains 5 mg of cetrimide (0.5% w/w) and 1 mg of chlorhexidine dihydrochloride (0.1% w/w) as the active ingredients.
Excipients with known effect:
Cetostearyl alcohol 10.00% w/w
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream
White, smooth homogeneous cream, free of lumps.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For cutaneous use only.
Apply the cream over the affected area after cleansing.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine digluconate-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

For external use only.
Avoid contact with the middle ear, meninges and other nervous tissue.
Savior Cream must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Savior Cream does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Savior Cream comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.
Keep all medicines away from children.
If symptoms persist, stop using and consult your doctor.
The product is incompatible with anionic substances (e.g. soap)

Information concerning excipients
Savior cream contains:
• Chlorhexidine which 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. Savior Cream 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).
• Cetostearyl Alcohol may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation
Pregnancy
There are no adequate data from the use of chlorhexidine digluconate and cetrimide in pregnant women.
The potential risk for humans is unknown but is most likely very low since chlorhexidine digluconate and cetrimide are poorly absorbed following topical application.
Breast-feeding
It is not known whether chlorhexidine digluconate and cetrimide are excreted in breast milk. There is no adequate data from the use of chlorhexidine and cetrimide in breast-feeding women. However, it is unlikely that the products are excreted in breast milk, since the products are poorly absorbed. After topical usage of the product, as a general precaution, rinse nipples thoroughly with water before breast-feeding.
Fertility
No data are available on fertility outcomes.

4.7 Effects on ability to drive and use machines
Savior has no influence on the ability to drive and use machines.

4.8 Undesirable effects
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: 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); or not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Immune system disorders
Very rare: Anaphylactic reaction
Very rare: Angioedema, urticaria
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).
Skin and subcutaneous tissue disorders
Very rare: Skin irritation
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters
Eye disorders
Frequency not known: Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment.

Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

Paediatric population

No investigations in children have been performed. However, frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Symptoms

While accidental ingestion is unlikely to cause any systemic effects due to the poor absorption of Chlorhexidine digluconate and cetrimide, ingestion of high concentrations may cause esophageal damage and necrosis with symptoms such as nausea and vomiting. Cetrimide has depolarising muscle relaxant properties and toxic symptoms include dyspnoea and cyanosis due to paralysis of the respiratory muscles, possibly leading to asphyxia. CNS depression (sometimes preceded by excitement and convulsions), hypotension, coma, and death may also occur.

Management

Treatment of poisoning is symptomatic; demulcents and diluents may be given if necessary but emesis and lavage should be avoided. Activated charcoal may be considered if the patient presents within an hour of ingestion.

Corticosteroids may reduce oropharyngeal edema.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine, combination - Pharmacotherapeutic group: Antiseptics and disinfectants, ATC Code: D08AC52

Chlorhexidine digluconate is an effective antiseptic with a wide range of activity against micro- organisms, including gram positive and gram negative bacteria, fungi and viruses.

Cetrimide is a quaternary ammonium compound with surfactant and antiseptic properties.

5.2 Pharmacokinetic properties

Chlorhexidine digluconate and cetrimide are poorly absorbed from the gastrointestinal tract and skin.

5.3 Preclinical safety data

There is minimal systemic absorption of chlorhexidine and cetrimide following topical administration. Preclinical data do not show genotoxic risk for chlorhexidine digluconate. Reproductive studies with chlorhexidine digluconate in animals have not revealed any teratogenic potential nor risk to the foetus. No additional information is available for cetrimide.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Mineral oil (Paraffin oil)
Purified water

6.2 Incompatibilities

Chlorhexidine is incompatible with anionic substances (e.g. soap, toothpaste).

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after opening: 12 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube with a screw cap.
Each package contains 1 tube of 10g.

6.6 Special precautions for disposal

Medicines should be kept out of the sight and reach of children.

7. MARKETING AUTHORISATION HOLDER

Teva Israel LTD, Israel
124 Dvora Hanevi'A ST. Tel Aviv 6944020,
Israel

8. REGISTRATION NUMBER(S)

126-25-21373

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