

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Savlon Antiseptic Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 0.5% w/w

Chlorhexidine Digluconate 0.1% w/w

1 gram of Savlon antiseptic cream contains 5 mg of cetrimide (0.5% w/w) and 1 mg of chlorhexidine digluconate (0.1% w/w) as the active ingredients.

Excipients with known effect:

Cetostearyl alcohol 10.00% w/w

Methyl parahydroxybenzoate (E218) 0.01% w/w

Propyl parahydroxybenzoate (E216) 0.01% w/w

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The cleansing and prevention of infection in all types of lesions, ranging from minor skin disorders or blisters, to minor burns and small wounds.

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 eyes, middle ear, meninges and other nervous tissue. If accidentally splashed into the eye, the open eye should be irrigated for at least 10 minutes.

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

Savlon cream contains:

- Cetostearyl Alcohol: May cause local skin reactions (e.g. contact dermatitis).
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).
- 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. Savlon 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).

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

Savlon 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 ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1,000$, $< 1/100$); rare ($\geq 1/10,000$, $< 1/1,000$); very rare ($< 1/10,000$); 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

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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
Liquid paraffin
Methyl hydroxybenzoate
Propyl hydroxybenzoate
Antiseptic perfume compound P2419
Disodium edetate
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

24 months.
Shelf life after opening: 12 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube with a screw cap.

Polyethylene/aluminium/polyethylene laminate tube with a multi-layer peel-off tamper evident seal composed of lacquer, aluminium and internal ionomer, closed screw cap.

Tubes may be further packaged in unit cardboard boxes. Boxed or unboxed tubes may be provided as items in first aid containers.

Pack sizes: 15, 30, 40, 60, and 100g.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,
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Brentford
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TW8 9GS
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0111

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

1 November 1997 / 04 January 2007

10 DATE OF REVISION OF THE TEXT

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