Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Savlon Antiseptic Cream Cetrimide 0.5% w/w Chlorhexidine Digluconate 0.1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:
Cetrimide 0.50% w/w
Chlorhexidine digluconate 0.10% w/w

Excipients:
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.
Smooth, white, homogenous cream with an antiseptic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For prevention and management of superficial infections in skin tissue including wounds and minor burns.

4.2 Posology and method of administration

For cutaneous use.

Apply the cream over the affected area after cleansing.

4.3 Contraindications

Hypersensitivity to chlorhexidine digluconate, cetrimide or to any of the excipient listed in section 6.1

4.4 Special warnings and precautions for use

For external use only.

Avoid contact with the eyes, ears, mouth or other mucosa.

If accidentally splashed into the eye, the open eye should be irrigated for at least 10 minutes.

If symptoms persist or condition worsens, discontinue use and consult a physician.

The product is incompatible with anionic substances (e.g. soap).
Information concerning excipients

Savlon cream contains:
- Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interactions

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 (see section 5.2).

Breastfeeding:
It is not known whether chlorhexidine digluconate or cetrimide is excreted in breast milk. There are no adequate data from the use of chlorhexidine digluconate or cetrimide in breastfeeding 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

Within each system organ class, the adverse drug reactions are presented in order of decreasing seriousness. The frequency categories for each adverse drug reaction include: 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). Not known (cannot be estimated from the available data). The listed adverse events have estimated frequencies from post-marketing reporting.

Immune system disorders:
Very rare: Anaphylactic reaction, angioedema, urticaria

Skin and subcutaneous tissue disorders:
Very rare: Skin irritation
Not known: Blisters

Paediatric population:
No investigations in children have been performed. However, frequency, type, and severity of adverse reaction 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms

While accidental ingestion is unlikely to cause any systemic effects due to poor absorption of chlorhexidine digluconate and cetrimide, ingestion of high concentrations may cause esophagal damage and necrosis with symptoms such as nausea and vomiting.

Management

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

Corticosteroids may reduce oropharyngeal edema.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and disinfectants, Chlorhexidine, combinations, 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 gastro- intestinal 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. Reproductive studies with chlorhexidine digluconate in animals have not revealed any teratogenic potential or risk to the foetus. No additional information is available for cetrimide.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Liquid paraffin
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Antiseptic Perfume Compound P2419
Disodium edetate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months
Shelf life after opening: 6 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube with 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.

Pack sizes: 15, 30, 33, 34.5, 36, 40, 60, 66, 100 and 120 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/324/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 June 1991

Date of last renewal: 26 June 2006

10 DATE OF REVISION OF THE TEXT

November 2019