

# Savlon Antiseptic Cream

Summary of Product Characteristics Updated 08-Jul-2014 | Novartis Consumer Health

## 1. Name of the medicinal product

Savlon® Antiseptic Cream

## 2. Qualitative and quantitative composition

Cetrimide 0.5% w/w

Chlorhexidine Gluconate 0.1% w/w

1 gram of Savlon antiseptic cream contains 5 mg of cetrimide (0.5% w/w) and 1 mg of chlorhexidine Gluconate (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.

A smooth, white, homogenous cream with an antiseptic odour.

## 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 topical use only.

Gently smear cream over the affected area.

### 4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-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.

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).
- 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 with the topical forms.

## 4.6 Fertility, pregnancy and lactation

### Pregnancy

There are no adequate data from the use of chlorhexidine and cetrimide in pregnant women.

The potential risk for humans is unknown but is most likely very low since chlorhexidine and cetrimide are poorly absorbed following topical application (see section 5.2).

### Breast-feeding

It is not known whether chlorhexidine 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

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

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.

## 4.9 Overdose

While accidental ingestion is unlikely to cause any systemic effects due to poor absorption of chlorhexidine and cetrimide, ingestion of high concentrations could cause irritation of the gastrointestinal mucosa/gastritis. Gastric lavage might be needed. Symptomatic treatment should be employed.

In case of overdose, seek medical attention or contact a poison control centre.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

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

Chlorhexidine 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 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. Reproductive studies with chlorhexidine gluconate 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  
Purified water

## 6.2 Incompatibilities

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

## 6.3 Shelf life

24 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, 33, 34.5, 36, 40, 60, 66, 100 and 120g.

## 6.6 Special precautions for disposal and other handling

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

# 7. Marketing authorisation holder

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# 8. Marketing authorisation number(s)

PL 00030/0122

## **9. Date of first authorisation/renewal of the authorisation**

1 November 1997

## **10. Date of revision of the text**

3<sup>rd</sup> June 2014

## **Legal category**

GSL

## **Company Contact Details**

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