Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Savlon Antiseptic Liquid.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 2.25 % w/v and Chlorhexidine Gluconate 0.225 % w/v.

Excipients: also includes benzyl benzoate 0.056% w/v

For a full list excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for Cutaneous Solution.

A clear, colourless or almost colourless liquid with a pine-like odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A topical antiseptic for prevention and management of infection or superficial skin trauma.

4.2 Posology and method of administration

For cutaneous use.

Two capfuls to ½ litre of warm water.

4.3 Contraindications

Hypersensitivity to chlorhexidine, cetrimide or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

If symptoms persist or condition worsens or if a skin reaction occurs, discontinue use and consult a doctor.

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 with water for at least 10 minutes.

Savlon Antiseptic Liquid contains benzyl benzoate which may be mildly irritant to the skin, eyes and mucous membranes.

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).

Breastfeeding
It is not known whether chlorhexidine and cetrimide are excreted in breast milk. There are 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 breastfeeding.

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: blistering

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.

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.

If swallowed, wash out mouth, drink plenty of milk or water and seek medical advice.

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

Clorhexidine and cetrimide are poorly absorbed from the gastro-intestinal tract and skin.

5.3 Preclinical safety data

There is minimal systemic absorption of chlorhexidine 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

Isopropyl alcohol
Terpineol
Liquid deodoriser
Benzyl benzoate
d-Gluconolactone
Sodium Hydroxide
Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Colourless (clear), or orange (clear), or blue (clear) blow moulded PVC bottles with polypropylene screw caps.

Pack sizes: 125 ml, 250 ml, 300 ml, 450 ml, 495 ml, 500 ml, 550 ml, 600 ml, 750 ml, 900 ml, 2.5 litres.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/139/001

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

July 2016