Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Savlon Antiseptic Wound Wash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate Solution 2.25% v/v, equivalent to chlorhexidine gluconate 0.45% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.
A clear, colourless liquid with a citrus odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the cleansing and prevention of infections of minor wounds and abrasions.

4.2 Posology and method of administration

For cutaneous use only.

Apply to affected area as required.

4.3 Contraindications

Hypersensitivity to chlorhexidine 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, middle ear, meninges and other nervous tissues.

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

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

Breastfeeding:
It is not known whether chlorhexidine is excreted in breast milk. There are no adequate data from the use of chlorhexidine in breastfeeding women. However, it is unlikely that the product is excreted in breast milk, since the product is 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 or 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 (<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, angiodema, 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 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 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

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

If swallowed, the mouth should be washed out and the patient instructed to drink plenty of water or milk, to seek medical advice immediately and to show the container to the doctor.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and disinfectants. **ATC Code:** D08AC02.

The product is a topical solution for external use and is not intended for internal use. No general pharmacological studies on chlorhexidine are available.

Because of its strongly cationic nature, the active agent chlorhexidine gluconate binds to skin surfaces, mucosa or tissues and is consequently poorly absorbed and its effects on internal organs are minimal.

If absorbed, there is no evidence of metabolic cleavage of the drug.

5.2 Pharmacokinetic properties

Chlorhexidine gluconate is very poorly absorbed from the gastrointestinal tract and skin and no detectable blood levels have been found in man following oral use.

Due to the binding properties of chlorhexidine gluconate, the pharmacokinetics of this formulation at the strength of 0.45% are not considered relevant.

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 effects or risk to the foetus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene polyoxypropylene block co-polymer
Lauryl dimethyl amine oxide
Herbacol 15393/T (perfume)
Polysorbate 20
D-gluconolactone
Sodium hydroxide
Purified water

6.2 Incompatibilities

For maximum benefit, do not use with soap.

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

PET container with snap pump spray
or
PVC bottle with polypropylene screw cap.

Pack sizes:
100, 125, 150 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Health (Ireland) Limited,
12 Riverwalk,
CityWest Business Campus,
Dublin 24,
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/133/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 1992

Date of last renewal: 27 November 2007

10 DATE OF REVISION OF THE TEXT

January 2017