Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Savlon Dry Antiseptic.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Spray powder containing 1.14% w/w of Povidone Iodine with an available iodine content of 5% w/w in the powder.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous spray, powder.

Pressurised Cutaneous Spray. Orange/brown micronised powder and propellants.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the topical prophylaxis and treatment of superficial infections or injuries of skin.

4.2 Posology and method of administration

Apply to the affected area by spraying from a distance of 15 to 22 cm.

Special populations;

Children: There are no special dosage recommendations for children. However, povidone-iodine is not recommended for regular use in neonates and is contra-indicated in very low birth weight infants (below 1500g).

Renal Impairment: Avoid regular application to inflammed or broken skin.

4.3 Contraindications

Savlon Dry is contraindicated in patients with thyroid disorders, in particular overactive thyroid (hyperthyroidism), nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis.

Hypersensitivity to povidone iodine or any other ingredient of the spray.

Povidone iodine containing products are contra-indicated for preterm neonates gestational age under 32 weeks.

Use near nose or mouth.

Scheduled radioiodine therapy.

4.4 Special warnings and precautions for use

Iodine absorption may interfere with tests of thyroid function.

Application to extensive areas of broken skin may lead to excessive absorption of iodine.

Regular or prolonged use should be avoided in patients receiving lithium therapy (refer to section 4.5).

Prolonged treatment with povidone-iodine in patients with severe and extensive burns may cause metabolic acidosis, hypernatraemia and renal impairment.

Special caution is needed in patients with pre-existing renal insufficiency and in neonates and infants up to 6 months of age, pregnant and breast-feeding women. In such cases benefit/risk assessment should be performed and monitoring of thyroid function should be considered.

Avoid application of povidone-iodine into the eyes and nose.

Care must be taken when povidone-iodine is used on known iodine sensitive subjects, although these subjects do not normally react to povidone-iodine.

4.5 Interaction with other medicinal products and other forms of interaction

Regular use should be avoided in patients on concurrent lithium therapy as this has been shown to exhibit additive hypothyroid effects with other iodine containing medicinal products.

Absorption of iodine from povidone iodine through either intact or damaged skin may interfere with thyroid function tests.

Do not mix or co-administer with disinfectants and/or antiseptics or other agents used for the treatment of wounds.

4.6 Fertility, pregnancy and lactation

Excessive use of Povidone-iodine should be avoided in pregnant or lactating women because iodine can cross the placental barrier and is secreted in breast milk. Although no adverse events have been reported from limited use, caution should be recommended and therapeutic benefit must be balanced against possible effects of the absorption on foetal thyroid function and development.

Fertility

No data is available on fertility outcomes.

4.7 Effects on ability to drive and use machines

Povidone-iodine has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The undesirable effects include hypersensitivity and localised skin reactions. In very rare instances, anaphylactic reactions and in predisposed patients Iodine-induced hyperthyroidism may occur.
The application of povidone–iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function. As the occurrence of these systemic adverse drug reactions is linked to certain circumstances (large wounds or severe burns), no frequencies can be provided.

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10) common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000) or unknown (can not be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Immune system disorders

Rare: Hypersensitivity
Very rare: Anaphylactic reaction
Endocrine disorders
Very rare: Hyperthyroidism
Metabolism and nutrition disorders
Unknown: Metabolic acidosis, hypernatraemia
Skin and subcutaneous tissue disorders
Rare: Skin reaction localised
Renal and urinary disorders
Unknown: Renal impairment

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

The amount of povidone-iodine contained in one aerosol can of Savlon Dry is unlikely to have any toxic effects if ingested.

Iodine ingested in large amounts can produce goitre and hypothyroidism as well as hyperthyroidism and may lead to a range of adverse effect: metallic taste, vomiting, abdominal pain and diarrhoea, thirst, headache and symptoms of shock (tachycardia, hypotension, fever, metabolic acidosis and renal impairment).

Treatment of iodine poisoning consists of gastric lavage with a starch solution (15 g starch or flour in 500 ml water); in severe cases, with sodium thiosulphate 1 - 5% as a specific antidote. Gastric irritation can be reduced with milk. Monitoring of the fluid and electrolyte balance should be useful.

High serum iodine levels resulting from excessive use can be reduced by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptic and disinfectant; ATC code: D08AG02

Povidone iodine is an antiseptic which liberates iodine in contact with the skin.

5.2 Pharmacokinetic properties

Povidone-iodine administered clinically via any route can result in systemic absorption of iodine. The amount of absorbed iodine will vary according to the concentration of the povidone-iodine preparation used, the number of applications and the route of administration. Whilst absorption of iodine may occur following topical administration of all povidone-iodine preparations, the effects are dose related. In view of the fact that a 10 second burst will deliver only 7mg of available iodine, the levels of iodine likely to be absorbed following administration of Savlon Dry will be exceedingly small and the effects on the internal organs is minimal.

Any increase in the blood iodine level is generally transient. In patients with a healthy thyroid, the increased iodine level does not lead to any clinically relevant changes in thyroid hormone status. When iodine metabolism is normal, increased amounts of iodine are excreted via the kidneys.

5.3 Preclinical safety data

The limited preclinical studies on povidone-iodine, including acute and chronic toxicity studies, do not indicate any special hazard at therapeutic doses. A mutagenic effect can be excluded for povidone-iodine. Carcinogenecity and reproductive toxicity studies are not available for povidone-iodine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
N-Pentane
Soya Lecithin
Butane 40

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

The canister contains a pressurised liquid.

PRESSURISED CONTAINER. Protect from sunlight.

DO NOT:
- expose to temperatures higher than 50°C.
- pierce or burn the canister even after use.
- spray on naked flame or flammable material.
- apply while you are smoking.

Keep away from sources of ignition.
Do not store above 25ºC

6.5 Nature and contents of container

Monobloc aluminium aerosol container, internally lacquered, containing micronised powder and propellants under pressure and fitted with a valve and actuator and transparent yellow polypropylene overcap.

Pack sizes: 50 ml and 150 ml.

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

PA0678/126/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation**:** 12 May 1986

Date of last renewal: 20 November 2006

10 DATE OF REVISION OF THE TEXT

July 2016