Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Salactol Collodion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 16.7%w/w
Lactic Acid 16.7%w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Collodion
Colourless or pale yellow evaporative collodion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of warts, verrucas, corns and calluses.

4.2 Posology and method of administration

For adults, children and the elderly.

Salactol should be applied once daily usually at night. It can take up to twelve (12) weeks for resistant lesions to disappear, and it is necessary to persevere with the treatment.
Soak the affected site in warm water and pat dry. Gently rub the surface of the wart, verruca, corn or callus with a pumice stone or manicure emery board to remove any hard skin. Using the applicator provided, carefully apply a few drops of Salactol to the lesion, allowing each drop to dry before applying the next one. Take care to localise the application to the affected area.
Plantar warts should be covered with an adhesive plaster. Leave for 24 hours. Repeat the procedure daily,after first removing any plaster.

4.3 Contraindications

Not to be used o or near the face, intertriginous or anogenital regions.
Not to be used by diabetics or individuals with impaired peripheral blood circulation.
Not to be used in cases of sensitivity to any of the ingredients.
Not to be used on moles, birthmarks, hairy warts or any other skin lesions for which it is not indicated.

4.4 Special warnings and precautions for use

Keep away from the eyes and mucous membranes.
The paint should be applied carefully to the wart,verruca, corn or callus only, to avoid possible irritation of surrounding normal skin.
Some mild, transient irritation may be expected, but in cases of more severe or persistent pain/irritation, the treatment should be suspended and/or discontinued. See also Section 4.8.
Keep out of the reach of children.
For external use only.
If accidentally swallowed, or splashed into the eye, immediately seek medical advice. Salactol contains evaporative solvents, so do not inhale vapour.
Extremely flammable.
Replace cap tightly after use.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Salactol may be irritant in certain patients, which in rare instances may appear as a temporary blemish on the skin. See also Section 4.4.

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

Any excessive use of Salactol could cause irritation of the skin. If this occurs, Salactol should be used more sparingly or applied less frequently. Accidental oral ingestion should be treated immediately by gastric lavage with a 2 to 5% aqueous sodium bicarbonate solution. Fluid and electrolyte balance should be monitored and appropriate supportive measures should be provided. Symptoms include headache, nausea, vomiting, diarrhoea and respiratory depression.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The combination of salicylic acid and lactic acid in flexible collodion has been shown to be particularly efficacious in treating warts, verrucas, corns and calluses.

Salicylic acid has bacteriostatic and fungicidal actions as well as keratolytic properties. Its effectiveness for topical treatment of hyperkeratotic skin lesions is based on mild keratolytic action which produces slow and painless destruction of the epithelium. In the treatment of warts, a mild irritant reaction, which may render the virus more prone to immunologic stimulation or response, may add to the mechanical removal of infected cells. Apart from its antiseptic and caustic properties, lactic acid enhances the availability of salicylic acid from the dried collodion.

5.2 Pharmacokinetic properties

Salactol contains 16.7% salicylic acid and 16.7% lactic acid in flexible collodion. The bioavailability of salicylic acid is reduced as the collodion film dries on the skin due to entrapment of the drug which inhibits release. The addition of lactic acid to salicylic acid collodion provides more efficient release of the salicylic acid, since the non-volatile lactic acid remains in the film, thus permitting continued release of the keratolytic which may otherwise be entrapped within the dried collodion film. Systemic absorption of salicylic acid or lactic acid after application to small circumscribed areas is exceedingly unlikely.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pyroxylin

Colophony
Castor Oil
Industrial Methylated Spirit
Ether

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Amber glass bottle with an HDPE screw cap and integral low density polyethylene spatula, containing 10 mls.

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

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 February 1981

Date of last renewal: 19 February 2006

10 DATE OF REVISION OF THE TEXT

December 2020