Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DUOFILM Cutaneous Solution
Salicylic Acid 16.7% w/w
Lactic Acid 15.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid	16.7	% w/w
Lactic Acid	15.0	% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.
Yellow to amber coloured, slightly viscous clear liquid having an ether odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

DUOFILM is indicated in the treatment of warts.

4.2 Posology and method of administration

For topical use only.

Adults, the elderly and children aged 2 years and over:

Children under 12 years should only use the product under supervision.

Duofilm should be applied to the affected areas only.

Duofilm should be applied to warts once daily, preferably at bedtime.

Procedure for application:

1. The wart should be soaked in warm water for 5 minutes and dried thoroughly with a clean towel.
2. The surface of the wart should be rubbed with a nail file, pumice stone, emery board or coarse washcloth, with care taken not to cause bleeding.
3. A thin layer of Duofilm should be applied directly to the wart. Care should be taken to avoid the healthy surrounding skin.
4. The solution should be allowed to dry thoroughly. The wart should be covered with a plaster (dressing) if it is large or if it is on the foot to help penetration of ingredients.

It is recommended that treatment continues until whichever of the following occurs first:

- The wart is completely cleared and the normal ridgelines of the skin have been restored.
- The wart has been treated for 12 weeks.

Clinically visible improvement should occur in 1-2 weeks, but the maximum effect may be expected after 4-8 weeks.

If wart persist beyond 12 weeks of treatment, the patient should be advised to consult their pharmacist or doctor.

Consider alternative treatments if warts cover a large area of the body (more than 5 cm^2).

Patients should be advised to consult a pharmacist or doctor if skin irritation develops.

Due to the flammable nature of salicylic acid and lactic acid solution, patients should avoid smoking or being near an open flame during application and immediately after use.

Infants under 2 years of age:
Treatment of infants under the age of 2 years is not recommended.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

Do not use on open skin wounds, moles, birthmarks, genital warts, warts on the face, or warts with hair growing from them, red edges, or unusual colour.

4.4 Special warnings and precautions for use

This medicinal product is for external use only.

Salicylic acid and lactic acid solution may cause eye irritation. Avoid contact with eyes and other mucous membranes (nose, mouth, genital and anal areas). In case of accidental contact with the eyes or other mucous membranes, flush with water for 15 minutes.

Avoid inhaling the vapour.

Avoid exposure to healthy skin. Duofilm may cause skin irritation. If undue skin irritation develops treatment should be discontinued.

Do not apply to reddened, inflamed or damaged skin.

Consider alternative treatments if warts cover a large area of the body (more than 5 cm^2) due to the potential risk of salicylate toxicity.

Duofilm is not recommended in patients with diabetes, circulatory problems or peripheral neuropathy except under the supervision of a doctor.

Oral salicylates taken during or immediately after a viral illness have been associated with Reye’s syndrome and hence there is a theoretical risk with topical salicylates. Therefore, do not use in children or teenagers during or immediately after chickenpox, influenza, or other viral infections.

Ensure this product is stored out of the sight and reach of children to avoid accidental ingestion.

4.5 Interaction with other medicinal products and other forms of interaction

Topical salicylic acid and lactic acid solution may increase the absorption of other topically applied medicines. Therefore, concomitant use of salicylic acid and lactic acid solution and other topical medicines on the treated area should be avoided. As systemic exposure of topically applied salicylic acid and lactic acid solution is low, interaction with systemically administered medicines is not anticipated.

4.6 Fertility, pregnancy and lactation

Pregnancy
The safety of salicylic acid and lactic acid solution during human pregnancy has not been established. Studies in animals given salicylic acid orally demonstrated embryo-toxicity at high doses *(see Non-Clinical Information).*

Salicylic acid and lactic acid solution is not recommended during pregnancy.

Lactation
Salicylates are excreted in human milk. Salicylic acid and lactic acid solution is not recommended during lactation.

If used or administered during lactation, care should be taken to avoid contact with the breast area in order to avoid accidental ingestion by the infant.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following convention is used for the classification of the frequency of an adverse reaction and is based on the CIOMS guidelines:

Very common:	≥1/10
Common:	≥1/100 to <1/10
Uncommon:	≥1/1000 to <1/100
Rare:	≥1/10000 to <1/1000
Very rare:	<1/10000
Not known:	(Cannot be estimated from the available data)

Clinical Trial Data

Immune system disorders
Common: Rash

Skin and subcutaneous tissue disorders
Very common: Application site reaction, pruritus, burning sensation, erythema, scaling, dryness
Common: Skin hypertrophy

Post Marketing Data

Immune system disorders
Rare: Application site hypersensitivity including inflammation

Skin and subcutaneous tissue disorders
Rare: Application site pain and irritation
Application site discoloration/skin discoloration
Exposure to healthy skin can lead to application site blistering and skin exfoliation
Allergic dermatitis

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

Symptoms and Signs
In the event of accidental oral ingestion symptoms of salicylate toxicity may occur. The risk of developing symptoms of salicylate poisoning or salicylism is increased if topical salicylic acid and lactic acid solution is used excessively or if it is used for prolonged periods of time. Therefore, duration of use and recommended frequency compliance is very important.

Treatment
Management should be as clinically indicated or as recommended by the national poisons centre, where available. There is no specific treatment for accidental oral ingestion of salicylic acid and lactic acid solution. If accidental oral ingestion occurs, the patient should be treated according to local guidelines with appropriate monitoring as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Wart and anti-corn preparations, ATC Code: D11AF.

Mechanism of Action

Topically applied salicylic acid is keratolytic. The keratolytic activity produces desquamation by solubilising the intercellular cement in the stratum corneum resulting in the shedding of skin scales.

Lactic acid affects the keratinisation process, reducing the hyperkeratosis which is characteristic of warts. At high concentrations it can cause epidermolysis, leading to the destruction of the keratotic tissue of the wart and of the causative virus. It also has antiseptic properties.

Flexible collodion provides a viscous vehicle that allows accurate application of the active ingredients to the wart. It also forms a film that helps to hydrate and promote the destruction of wart tissue.

5.2 Pharmacokinetic properties

Absorption

Salicylic acid is absorbed through the skin; where detectable, maximum plasma levels are found 6 to 12 hours after application. Systemic absorption of salicylic acid has been reported to range from 9% to 25% after topical application of other salicylic acid-containing preparations. The extent of absorption is variable depending on the duration of contact and the vehicle. Despite percutaneous absorption, the systemic exposure is low given the low dose topically administered to small, localised areas of hyperkeratotic tissue.

Human abdominal skin in a flow-through diffusion system was used to assess the in vitro percutaneous absorption of lactic acid. At a pH of 3, the amount of radioactivity detected in the receptor fluid, stratum corneum, epidermis, and dermis was 3.6, 6.3, 6.6, and 13.9%, respectively.

Distribution

Following percutaneous absorption, salicylic acid is distributed in the extracellular space; approximately half of which is protein bound to albumin.

Metabolism

Salicylates are metabolised in the liver by microsomal enzymes to salicyluric acid and phenolic glucuronides of salicylic acid. That which is not metabolised is excreted in the urine as unchanged salicylic acid.

Elimination

Within 24 hours of salicylic acid being absorbed and distributed in the intercellular space, approximately 95% of the absorbed dose can be recovered in the urine.

5.3 Preclinical safety data

See section 4.6.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Flexible Collodion BP
(contains pyroxylin, colophony, virgin castor oil, ethanol and ether).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep away from naked flame.

6.5 Nature and contents of container

Duofilm is supplied in amber bottles of 15 ml fitted with a brush applicator.

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

PA0678/114/001

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Date of last renewal: 21st January 2007

10 DATE OF REVISION OF THE TEXT

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