

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Duofilm

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid 16.7% w/w

Lactic acid 15% w/w

Excipient(s) with known effect

Flexible Collodion

(Contains colophony and ethanol (10% v/v))

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for topical administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Duofilm is indicated for the treatment of warts.

4.2 Posology and method of administration

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

Apply daily to the affected areas only.

Children:

Children under the age of 12 years should be treated under supervision.

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

Duofilm should be applied to the wart 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:

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

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

If warts 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 cm²) (see Warnings and Precautions).

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

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

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Do not use on open wounds, irritated or reddened skin, or any area that is infected.

Duofilm should not be used on the face, anogenital regions, moles, birthmarks, mucous membranes, warts with hair growing from them, red edges or an unusual colour. Avoid applying to normal skin.

4.4 Special warnings and precautions for use

Duofilm contains colophony which may cause allergic contact dermatitis. This medicine contains 10% v/v ethanol in each application. It may cause burning sensation on damaged skin.

Duofilm may cause eye irritation. Avoid contact with eyes and other mucous membranes. In case of accidental contact with the eyes or other mucous membranes, flush with water for 15 minutes.

Avoid exposure to healthy skin (see Adverse Reactions). Duofilm may cause skin irritation. If undue skin irritation develops treatment should be discontinued.

Consider alternative treatments if warts cover a large area of the body (more than 5 cm²) 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, use is not advised in children or teenagers during or immediately after chickenpox, influenza, or other viral infections.

It has been reported that salicylates are excreted via breast milk (see *Pregnancy and Lactation*).

Patients should be advised not to inhale the vapour.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, Pregnancy and lactation

Pregnancy

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

Duofilm is not recommended during pregnancy.

Lactation

Salicylates are excreted in human milk. Duofilm 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

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$) and very rare ($< 1/10,000$), including isolated reports.

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 (*see Warnings and Precautions*).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 Duofilm 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code

Pharmacotherapeutic group: Wart and anti-corn preparations.

ATC code: D11AF

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.

Salicylic acid is keratolytic, producing desquamation by solubilising the intercellular cement in the stratum corneum resulting in the shedding of skin scales.

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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Flexible Collodion

(Contains pyroxylin, colophony, virgin castor oil, ethanol and ether)

6.2 Incompatibilities

None.

6.3 Shelf life

a) For the product as packaged for sale

3 years

b) After first opening the container

Comply with expiry date

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Amber screw capped applicator bottle containing 15ml.

6.6 Special precautions for disposal

There are no special instructions for use or handling of Duofilm.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.

Linthwaite,

Huddersfield,

HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0551

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

14/02/1990

10 DATE OF REVISION OF THE TEXT

25/06/2021