

# ACTIL<sup>LOTION</sup>

(Salicylic Acid + Lactic Acid)

## COMPOSITION:

Each gram contains:  
Salicylic Acid ..... 167mg  
Lactic Acid ..... 167mg

## (Innovator's Specifications)

## DESCRIPTION:

Actil lotion contains two drugs called salicylic acid and lactic acid. It works by softening the skin of a wart, causing it to peel off. Warts are typically small, rough, hard growths that are similar in color to the rest of the skin. They typically do not result in other symptoms, except when on the bottom of the feet, where they may be painful. While they usually occur on the hands and feet, they can also affect other locations. One or many warts may appear. They are not cancerous.

Callus is an area of thickened skin that forms as a response to repeated friction, pressure, or other irritation. Since repeated contact is required, calluses are most often found on the feet and hands, but they may occur anywhere on the skin. Some degree of callus, such as on the bottom of the foot, is normal. Corn is a distinctively shaped callus of dead skin that usually occurs on thin or hairless and smooth skin surfaces, especially on the dorsal surface of toes or fingers. They can sometimes occur on the thicker skin of the palms or bottom of the feet.

## MECHANISM OF ACTION:

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.

## INDICATIONS:

Actil is indicated for the treatment of warts. It is also used to help remove corns and calluses.

## DOSEAGE & 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.

Actil should be applied to the wart once daily preferably at bedtime.

# ایکٹیل لوشن

(سیلیسیک ایسڈ + لیکٹک ایسڈ)

## 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 Actil 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 cm<sup>2</sup>). Patients should be advised to consult a pharmacist or doctor if skin irritation develops. Due to the flammable nature of Actil, patients should avoid smoking or being near an open flame during application and immediately after use.

## PHARMACOKINETICS:

### 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.

## WARNINGS & PRECAUTIONS:

Actil contains colophony which may cause allergic contact dermatitis. Actil 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. Actil 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 cm<sup>2</sup>) due to the potential risk of salicylate toxicity. Actil 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. Patients should be advised not to inhale the vapor. Keep out of the sight and reach of children.

## Pregnancy

The safety of Actil during human pregnancy has not been established. Studies in animals given salicylic acid orally demonstrated embryo toxicity at high doses. Actil is not recommended during pregnancy.

## Lactation

Salicylates are excreted in human milk. Actil 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.

## SIDE EFFECTS:

Rash, application site reaction, pruritus, burning sensation, erythema, scaling, dryness, Skin hypertrophy, application site hypersensitivity including inflammation, application site discoloration/skin discoloration, exposure to healthy skin can lead to application site blistering and skin exfoliation.

## DRUG INTERACTIONS:

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

## CONTRAINDICATIONS:

Hypersensitivity to the active substances or to any of the excipients. Do not use on open wounds, irritated or reddened skin, or any area that is infected. Actil 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.

## STORAGE & INSTRUCTIONS:

Caution: Highly Inflammable. Keep Away From Naked Flame. Do not store above 25°C. Do not freeze or refrigerate. Protect from heat, sunlight and moisture. Keep away from the reach of the children. Do not use on face and anogenital regions.

**To be sold on the prescription of a registered medical practitioner only.**

**FOR EXTERNAL USE ONLY.**

## HOW SUPPLIED

Actil lotion: 15ml in amber glass bottle with applicator.

## خوراک و ہدایات:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔ دو کو ۲۵ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔ دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

**PHARMASOL**

**PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,  
Lahore, Pakistan.