

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Scholl Corn and Callous Removal Liquid
Scholl Medicated Corn and Callous Removal Liquid
Seal and Heal Verruca Removal Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	% w/w
Salicylic Acid EP	12.50
Camphor BP	3.11

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Topical solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of corns, calluses, common warts and plantar warts (verrucae).

4.2 Posology and method of administration

Posology

Treatment may be continued for up to twelve weeks except on medical advice.

Adults:

Apply directly to the callus, corn, verruca or wart twice a day.

Paediatric Population

Children over 12 years:

As above for adults.

Children aged under 12 years of age:

Not recommended for children under twelve.

Method of Administration

For best results the feet should be washed and dried before use. The healthy skin around the area to treat should be protected with soft paraffin. The product should be applied directly to the wart, verruca, callous or corn twice a day, until the wart, verruca callous or corn has been removed.

No distinction is made between different categories of patient.

4.3 Contraindications

Not to be used by diabetics or those with severe circulatory disorders or suffering from neuropathy, except following a doctor's permission and recommendation.

Not to be used in patients who are hypersensitive to salicylic acid (or other NSAIDs), camphor or to any excipients in section 6.1.

Not to be used if the corn, callous, wart, verruca or surrounding skin is broken or inflamed.

Not to be used by pregnant or breastfeeding patients (see section 4.6)

When indicated for the treatment of warts and verruca, the product must not be used on moles, birthmarks, hairy or genital warts. It must not be used on the face or anogenital skin, mucosa or large areas of the body.

Not to be used in children under 12 years.

4.4 Special warnings and precautions for use

Discontinue use and remove any dressing if excessive discomfort or irritation is experienced or if sensitivity develops.

If the liquid comes into contact with normal skin wash off immediately with copious water.

Do not apply to normal skin or skin which is inflamed or broken.

For external use only.

This product contains the excipient Caster Oil which may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Salicylic acid can increase the penetration of topical drugs into the skin.

4.6 Fertility, Pregnancy and lactation

Pregnancy:

There is no data on the use of topical salicylic acid or camphor in pregnant women, therefore the use of this product during pregnancy is contraindicated.

Breast feeding:

Salicylates should be given with caution to breast-feeding mothers because of the possible risk of Reye's syndrome in nursing infants and there is no data on the use of topical camphor in breast feeding women. Therefore the use of this product during breast feeding is contraindicated.

Fertility:

There is no information on the effects of topical salicylic acid or camphor and fertility.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Local irritation or dermatitis may occur. if applied to normal healthy skin surrounding the callous. This may be controlled by temporarily discontinuing use and by carefully applying only to the verruca, corn or callus when the treatment is resumed.

Adverse events which have been associated with salicylic acid and camphor are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ and $< 1/1000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not Known	Hypersensitivity ¹

Skin and Subcutaneous Tissue Disorders	Not Known	Dermatitis Contact
General Disorders and Administration Site Conditions	Not Known	Application Site Reaction

Description of Selected Adverse Reactions

¹ Hypersensitivity reactions include urticaria, anaphylaxis and erythema multiforme.

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

Salicylic acid is readily absorbed through the skin, and symptoms of acute systemic salicylate poisoning have been reported after excessive use. Symptoms include thirst, lethargy, dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, tachypnoea, psychiatric disturbances and confusion.

Camphor is readily absorbed through the skin but the volume of absorption is relatively low. However, if accidental overdose does occur it can lead to nausea, vomiting, epigastric pain, headache, dizziness, oropharyngeal burning, delirium, muscle twitching, epileptiform convulsions, depression of the CNS and coma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatological preparations; Wart and anti-corn preparations; ATC classification is D11 AF.

The overall action of Corn and Callous Removal Liquid is that of keratolytic, due to the presence of salicylic acid. Camphor provides an additional effect of mild analgesia due to its counter irritant properties.

Mechanism of action

The mechanism of salicylic acid has not been established.

Pharmacodynamic Effects

Salicylates have analgesic, anti-inflammatory and antipyretic properties much of which is ascribed to an inhibition of prostaglandin synthesis. However, the relevant pharmacodynamic effect of Salicylic acid for this product is its “keratolytic” action.

The mechanism of this effect has been investigated in animals and in man, and appears to be due to a lipid modifying effect in the lipid bilayers of the skin rather than a keratolytic action. It is thought that the salicylic acid increases lipid structure fluidity so allowing moisture to penetrate into the areas surrounding the corn. This in turn leads to a pressure build up causing the corn to be pushed upwards.

Camphor has a number of actions including, respiratory stimulation, expectorant and calmative properties. However, the relevant pharmacodynamic action of camphor in this product is its counter-irritant property.

5.2 Pharmacokinetic properties

Salicylic acid can be absorbed following topical application. Plasma salicylate is largely protein-bound and is metabolised by oxidation and conjugation with some excreted unchanged. The elimination of salicylate follows first order kinetics with a half life of about four hours except with high systemic doses which result in saturation of the elimination mechanism.

Camphor is readily absorbed from all administration sites. Once absorbed it is hydrolylated in the liver to yield hydroxy-camphor metabolites, which are then conjugated with glucuronic acid and excreted in the urine.

5.3 Preclinical safety data

Salicylic Acid has a low acute toxicity with oral LD₅₀ values of 480mg/kg in the mouse and 891mg/kg in the rat. It is a dermal irritant but systemic toxicity from application of 12.5%W/W Salicylic Acid is extremely unlikely because of the small quantities applied.

Camphor has a high toxicity with a probable human lethal dose from 50mg/kg to 500mg/kg. Intraperitoneal LD₅₀ of 3000mg/kg has been reported in mice. Ingestion of camphor can lead to nausea, vomiting, mental confusion, delirium, clonic convulsions, coma, respiratory failure, and death in humans.

Relevant safety data however, relates to the topical use of camphor in adults. Camphor is a known irritant, with cases of non-immunological contact urticaria being reported following cutaneous use. The dose presented in Corn and Callous Removal Liquid is 2.8% W/V giving a total of 0.28mg in 10ml of the finished product. At this dosage it is unlikely that toxicity will occur.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pyroxylin HSE

Virgin Castor Oil EP

Methoxyisopropanol HSE

Acetone EP

6.2 Incompatibilities

Not relevant

6.3 Shelf life

Bottles: 5 years

Aluminium Tubes: 2 years

6.4 Special precautions for storage

Do not store above 25°C

Keep out of the reach of children

6.5 Nature and contents of container

Container: Glass bottle fitted with a polypropylene tamper evident cap and applicator

Contents: Each bottle contains 10ml

Container: An annealed aluminium tube with internal laquer, fitted with a tamper evident HDPE cap, with cardboard outer carton

Contents: Each tube contains 5ml

6.6 Special precautions for disposal

No special precautions

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 56058/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/09/1990

10 DATE OF REVISION OF THE TEXT

27/01/2025