Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scholl Corn and Callous Removal Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid	11.25	% w/w
Camphor, Racemic	2.8	% w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution (cutaneous liquid)
A white to slightly yellow viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the removal of corns and callouses.

4.2 Posology and method of administration

Adults and children over 12 years

Topical use

For the best results the feet should be washed and dried before use. The product should be applied directly to the corn or callous twice a day, until the corn or callous can easily be removed. Treatment may be continued for up to twelve weeks except on medical advice.

No distinction is made between different categories of patient.

Children

Not recommended for children under 12 years of age, except following a doctor’s recommendation.

4.3 Contraindications

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

Not to be used by those sensitive to salicylic acid or any of the other constituents of the product.
Not to be used if the corn, callous or surrounding skin is broken or inflamed.
The product must not be used on moles, birthmarks, hairy or genital warts. It must not be used on the face or anogenital skin or mucosa.

4.4 Special warnings and precautions for use

Do not allow contact with the eyes, mucosa or intact skin.
Discontinue use and remove any dressing if excessive discomfort is experienced.
If the liquid comes into contact with normal skin wash off immediately with copious water.
Do not apply to normal skin.
For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant to cutaneous use.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and during lactation has not been established.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Local irritation or dermatitis may occur.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC classification is D11F A.

The overall action of Corn and Callous Removal Liquid/Seal and Heal Verruca Removal Gel 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 that a keratolytic action. It is thought that the salicylic acid increases lipid structure fluidity so allowing moisture to penetrate into areas surrounding the corn. This in turn leads to a pressure build up forcing 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 conjunction 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 hydroxylated in the liver to yield hydroxyl-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 LD_{50} values of 480mg/kg in the mouse and 891mg/kg in the rat. It is 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 doses from 50mg/kg to 500mg/kg. Intraperitoneal LD_{50} 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

Pyroxlin
Castor Oil
Acetone
Methoxyisopropanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep cap firmly closed.

6.5 Nature and contents of container

Container: Amber glass bottle (Ph. Eur. Type III) with polypropylene tamper evident cap and applicator.
Contents: Each bottle contains 10ml.

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

Scholl Consumer Products Ltd.
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Trafford Park
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United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 455/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 1987

Date of last renewal: 23 June 2007

10 DATE OF REVISION OF THE TEXT

June 2010