

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Scholl Verruca Removal System 40% w/w Medicated Plasters

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## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Salicylic acid 40.00% w/w

For the full list of excipients, see section 6.1

## **3 PHARMACEUTICAL FORM**

Medicated Plaster

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For the treatment of common warts on the feet and hands.

Topical application to the skin

### **4.2 Posology and method of administration**

Posology

Treatment should not continue for more than twelve weeks, except under medical advice.

Adults: 1 medicated disc to the affected area every 48 hours.

#### Paediatric Population

Children aged 16 years and over:

As above for adults

Children aged under 16 years of age:

Should not be used in children under 16 years.

#### **Method of administration**

For best results the feet should be washed and dried before use. Select a medicated disc from those supplied which best fits the size of the wart. Leave medicated disc in place on wart for 48 hours and repeat treatment.

### **4.3 Contraindications**

- Not to be used by diabetics or patients or patients with severe circulatory disorders or suffering from neuropathy.
- Not to be used if the wart or surrounding skin is broken or inflamed.
- Not to be used on moles, birthmarks, warts with hair growing from them, genital warts or warts on the face or mucous membranes or to large areas of the body.
- Not to be used in patients who are hypersensitive to salicylic acid (or other NSAIDs) or to any excipients in section 6.1
- Not to be used by pregnant or breastfeeding patients (see section 4.6)
- Not to be used in children under 16 years.

### **4.4 Special warnings and precautions for use**

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

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

For external use only.

#### **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 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 salicylic acid in breast feeding women. Therefore the use of this product during pregnancy is contraindicated.

##### **Fertility:**

There is no information on the effects of topical salicylic acid 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 wart. This may be controlled by temporarily discontinuing use and by carefully applying only to the wart when the treatment is resumed.

Adverse events which have been associated with salicylic acid 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.

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
Immune System Disorders	Not Known	Hypersensitivity <sup>1</sup>
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**

<sup>1</sup> Hypersensitivity reactions include urticarial, anaphylaxis and erythema multiform.

### **Reporting of Suspected Adverse Reaction**

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](http://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.

### **Management**

In cases of overdose the product should be discontinued and supportive treatment given.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: other dermatological preparations; Wart and anti-corn preparations; ATC Code: D11AF

### Mechanism of Action

The mechanism of action of salicylic acid has not been established.

### Pharmacodynamics 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 reduction of intercellular cohesion and/or increasing endogenous hydration. The exact mechanism of action however has not yet been elucidated.

## **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.

## **5.3 Preclinical safety data**

Salicylic acid has a low acute toxicity with oral LD<sub>50</sub> values of 480mg/kg in the mouse and 891 mg/kg in the rat. It is a dermal irritant but systemic toxicity from application of Scholl Verruca Removal System is extremely unlikely because of the small quantities applied.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Polyvinyl alkyl ether (Low Molecular Weight)

Polyvinyl alkyl ether (High Molecular Weight)

Titanium dioxide

Liquid paraffin

4, 4'-Thiobis (2-tert-butyl-5-mehtylphenol)

Red iron oxide

Black iron oxide  
Backing material  
Twill cloth  
Polyethylene foam-coated plaster (closed cell)

## **6.2 Incompatibilities**

Not relevant

## **6.3 Shelf life**

3 years unopened.  
6 weeks after first opening.

## **6.4 Special precautions for storage**

Store below 25°C

## **6.5 Nature and contents of container**

Sachet

Contents: Three separate sachets each containing fifteen medicated adhesive discs. Each set of fifteen discs comprised of three sizes of disc (3x 5).  
Each pack contains fifteen cover plasters.

These may be composed of an ecru coloured twill cloth for the standard product or tan coloured closed cell polyethylene foam coated plasters for the washproof variant. Both types of plaster are coated with a pressure sensitive adhesive.

## **6.6 Special precautions for disposal**

Any unused medicinal product or waste should be disposed of in accordance with local requirements.

**7      MARKETING AUTHORISATION HOLDER**

**Scholl's Wellness Company Limited**  
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**8      MARKETING AUTHORISATION NUMBER(S)**

PL 56058/0004

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

27<sup>th</sup> June 1994 / 26<sup>th</sup> June 1999

**10     DATE OF REVISION OF THE TEXT**

08/10/2025