

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soft-Corn Removal Pads

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each plaster contains Salicylic acid 12 %w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

A latex coated textile uniformly spread with a synthetic adhesive containing salicylic acid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of soft corns between the toes.

4.2 Posology and method of administration

Adults

For the best results the feet should be washed and dried before use. One medicated disc should be placed on the corn, covered with a plaster. This should be repeated daily until the corn can be removed. Treatment should not continue for more than two weeks, except following a doctor's recommendation.

No distinction is made between different categories of patient.

Children

Not recommended for children under 16 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 or surrounding skin is broken or inflamed.

4.4 Special warnings and precautions for use

Discontinue use and remove plaster if excessive discomfort is experienced.

Do not apply to normal skin.

For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant.

4.6 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

Pharmacotherapeutic Group: Wart and anti-corn preparations.

ATC code: D11AF.

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 areas surrounding the corn. This in turn leads to a pressure build up causing the corn to be pushed upwards. It has been suggested that the occlusive nature of the plaster enhances this effect.

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 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%w/w salicylic acid adhesive mass 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 (E171)
Liquid Paraffin
4, 4'-ThioBis-2 - Tertbutyl-5-Methylphenol
Red Iron Oxide (E172)
Backing Material

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Sachet Contents:

4 medicated adhesive plasters mounted onto a silicone backed paper.
4 cover plasters mounted onto a silicone-backed paper.

Outer container:

Polypropylene flow wrap or cardboard carton.

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

Apply medicated disc to corn fabric side uppermost. Cover with pad and fix with strap.

7 MARKETING AUTHORISATION HOLDER

Scholl Consumer Products Ltd
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LU1 3LU
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8 MARKETING AUTHORISATION NUMBER

PA 455/6/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 24 June 2002

10 DATE OF REVISION OF THE TEXT

March 2006