Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scholl Corn Removal Medicated Plasters 40% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated plaster contains salicylic acid 40% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster
Light brown plaster with separate dark brown salicylic disc.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of corns

4.2 Posology and method of administration

Topical application to the skin

Adults and Children aged 16 years and over

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 cover plaster or pad. This should be repeated daily until the corn can be removed. Treatment should not continue for more than two weeks, except under medical advice.

Should not be used in children under 16 years, except following a doctor's recommendation.

4.3 Contraindications

- Not to be used by diabetics or patients with severe circulatory disorders or suffering from neuropathy, , except following a doctor's prescription and recommendation.
- Not to be used if the corn or surrounding skin is broken or inflamed.
- Not to be used on patients who are hypersensitive to salicylic acid or (to other NSAIDs) or to any excipients in section 6.1
- Not to be used by pregnant or breast feeding patients (see section 4.6)
- Not suitable for application to face, ano-genital region, or large areas of the body.

4.4 Special warnings and precautions for use

This product contains salicylic acid and so should be used with caution in patients at increased risk of developing salicylate adverse effects.

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

If there is aggravation of the condition or no improvement the doctor should be consulted.

Do not apply to normal skin.

For external use only

4.5 Interaction with other medicinal products and other forms of interaction

Salicylates in the form of gels, oils, or ointment applied to the skin have been found to increase the effects of warfarin. Bleeding and bruising, and/or raised INRs have been seen with both high and low doses of topical salicylates.

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 not be given 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 breast feeding 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 corn. This may be controlled by temporarily discontinuing use and by carefully applying only to the corn when the treatment is resumed.

4.9 Overdose

Salicylic acid is readily absorbed through the skin, and symptoms of acute systemic salicylate poisoning have been reported after excessive use. Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, and confusion, and may be controlled by reducing the dosage.

Patients should be given supportive therapy or treatment for Salicylate poisoning as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic acid: Keratolytic agent

Pharmacotherapuetic classification (ATC code): D11 AF

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.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl Alkyl Ether (Low Molecular Weight)
Polyvinyl Alkyl Ether (High Molecular Weight)
Titanium Dioxide
Liquid Paraffin
Antioxidant: 4,4'-thio-bis (2-tert-butyl-5-methylphenol)
Red Iron Oxide
Black Iron Oxide
Backing material

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life in products containing the medicated adhesive packaged for sale

3 years.

Shelf-life after first opening the container

6 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Container: Sachet (polyvinylidene chloride coated polyropylene film).

Plasters:
Sachet contents: 4, 6 or 8 medicated adhesive plasters mounted onto a silicone backed paper. 4, 6 or 8 cover plasters mounted onto a silicone backed paper.

Pads:
Sachet Contents: 4 or 6 medicated adhesive discs mounted onto a silicone backed paper. 4 or 6 twill cloth or silicon "polymer gel" cover pads with pressure sensitive adhesive mounted onto a silicone backed paper.

Outer container: polypropylene flow wrap or cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Scholl Consumer Products Ltd
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1 Old Park Lane
Trafford Park
Manchester
M41 7HA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 455/7/1

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 2013