IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0455/006/003
Case No: 2035470

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Scholl Consumer Products Limited

Venus, **1 Old Park Lane**, **Trafford Park**, **Manchester**, **M41 7HA**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Callous Removal Pads

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **24/06/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Callus Removal Pads

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid	40.00 % w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plasters
A medicated plaster mounted on a silicone-backed paper.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of callouses.

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 callous, covered with a cover plaster. This should be repeated daily until the callous can be removed. Treatment should not continue for more than two weeks, except under medical advice.

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 callous 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 to cutaneous use.

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:
Keratolytic.

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 callous. This in turn leads to a pressure build up causing the callous 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 LD_{50} values of 480 mg/kg in the mouse and 891 mg/kg in the rat. It is a dermal irritant but systemic toxicity from application of 40 %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
Liquid Paraffin
4,4’ Thio-Bis-2-Terbutyl-5-Methylphenol
Red Iron Oxide
Black Iron Oxide
Backing material

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened

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

Sachet contents: 2, 4 or 6 medicated adhesive plasters 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

6.6 Special precautions for disposal and other handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 455/6/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last renewal: 24 June 1987

Date of last renewal: 24 June 2007

10 DATE OF REVISION OF THE TEXT

April 2009