

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scholl Antiseptic Foot Balm

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | |
|-------------------|-----------|
| Halquinol | 0.4 % w/w |
| Methyl Salicylate | 0.5 % w/w |
| Menthol | 0.1 % w/w |

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream

Milky-white in colour, homogenous, with an odour of menthol and wintergreen.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of foot discomfort and tenderness associated with excessive perspiration, bunions, cracked skin and chilblains.

4.2 Posology and method of administration

Smooth in balm all over feet and between the toes. Use night and morning. For best results bathe and dry feet first.

Method of Administration: For topical application.

No distinction is made between different categories of patient.

4.3 Contraindications

Not to be used by diabetics, except with a doctor's permission.

Not to be used by patients sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

If the condition persists or is aggravated consult the doctor.

Not to be used by diabetics, except with a doctor's permission.

Keep out of reach of children. For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant to topical use.

4.6 Pregnancy and lactation

Safety of use during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Not relevant to topical use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

The product is an antiseptic cream for topical use. Pharmacodynamics and pharmacokinetics are not relevant for topical dosage form.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Emulsifying Wax
Propyl para-hydroxybenzoate
Purified Water
Triethanolamine
Sorbic Acid
Methyl para-hydroxybenzoate
Propylene Glycol

6.2 Incompatibilities

Not relevant.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Container: Aluminium tube.

Contents: 25 g or 30 g of a milky-white homogeneous cream with an odour of menthol and wintergreen.

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 precautions.

7 MARKETING AUTHORISATION HOLDER

Scholl Consumer Products Limited

Tubiton House

Oldham OL1 3HS

United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 455/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 1987

Date of last renewal: 23 June 2002

10 DATE OF REVISION OF THE TEXT

June 2002