

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scholl Athlete's Foot Spray Liquid.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 0.068% w/w (to deliver 1% w/v to the skin)

Excipient: Butylhydroxytoluene (E321) 0.007% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

Clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of athlete's foot.

As a fungistat in the topical treatment of infections due to dermatophytes sensitive to this agent including microspora, epidermophyta and trichophyta.

4.2 Posology and method of administration

Cutaneous Use.

For best results the feet should be washed and dried before use. Shake can before use. Point nozzle towards the affected area, holding it 10 – 15cm away. Spray liberally over the affected area, holding it 10-15cm away. Use twice a day, morning and night. Treatment may be continued for two weeks after symptoms disappear.

Adults and children:

Recommended dose: spray liberally on infected area twice daily. Continue treatment for two weeks after symptoms disappear.

4.3 Contraindications

Not recommended for nail or scalp infections.

Hypersensitivity to the active substance or any of the excipients in section 6.1.

4.4 Special warnings and precautions for use

For external use only

Keep out of eyes

If symptoms do not improve within 10 days, discontinue use and consult your doctor.

Keep out of the reach and sight of children.

Contains the excipient Butylated hydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Extremely flammable.

Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use.

Do not spray on naked flame or incandescent material.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:

Unknown: Skin Reactions, Skin Irritation, Pruritus, Contact Dermatitis

4.9 Overdose

Not relevant to topical use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tolnaftate, ATC code: D01 AE18.

Mechanism of action

Tolnaftate is an antifungal agent for topical use. Pharmacodynamic and pharmacokinetics are not relevant for a topical dosage form.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Polyethylene-propylene glycol monobutyl ether
Ethanol
Butane
Propane
Isobutane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Do not store above 25°C. The canister contains a pressurised liquid. Do not expose to temperatures higher than 50 °C. Do not pierce the canister.

6.5 Nature and contents of container

Internal epoxyenamel lacquered tinplate aerosol container with delivery nozzle containing a clear, colourless to slightly yellow solution 150 ml.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Scholl Consumer Products Limited
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8 MARKETING AUTHORISATION NUMBER

PA 0455/001/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 November 1986

Date of last renewal: 19 November 2006

10 DATE OF REVISION OF THE TEXT

May 2013