

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% to the skin).

Excipients with known effects:

Ethanol 35.8 % w/w

Butylated hydroxytoluene (E321) 0.007% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Topical spray

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of Athlete's Foot

4.2 Posology and method of administration

Posology

Adults:

Recommended Dose: Twice daily, in the morning and at night.

Treatment should continue for up to two weeks after the symptoms disappear.

Paediatric population:

Children aged 2 years and over: As above for adults.

Children under 2 years old: Not recommended for children under 2 years unless advised by a health care professional.

Method of administration

Topical.

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.

Wear clean socks or hosiery.

Apply liberally to the affected area.

4.3 Contraindications

Contraindicated in nail or scalp infections.

Hypersensitivity to the active substance or to any of the excipients listed 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.

Flammable, pressurised container. Protect from direct sunlight and do not expose to temperatures exceeding 50°C. Do not spray on naked flame or incandescent material. Do not pierce or burn even after use.

Contains butylated hydroxytoluene (E321). May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This medicine contains 35.8% w/w alcohol (ethanol). It may cause burning sensation on damaged skin.

If irritation or rash occurs, use of the product should be discontinued and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Pregnancy:

No effects during pregnancy are anticipated since systemic exposure to tolnaftate is negligible. Tolnaftate can be used during pregnancy.

Breast-feeding:

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of breast-feeding women to tolnaftate is negligible. Tolnaftate can be used during breast-feeding. Application onto the breast is not recommended during breast feeding.

Fertility:

No data on human fertility is available

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse reactions which have been associated with Tolnaftate have been ranked under headings of system organ class and frequency. Frequencies are defined using the following convention:

Very common	$\geq 1/10$
Common	$\geq 1/100$ to $\geq 1/10$
Uncommon	$\geq 1/1,000$ to $< 1/100$
Rare	$\geq 1/10,000$ to $< 1/1,000$
Very rare	$< 1/10,000$
Not known	(cannot be estimated from the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Skin and Subcutaneous Tissue Disorders	Not Known	Skin reaction, skin irritation, pruritus, dermatitis contact.

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:

There have been no reports of over dosage with the use of this product.

Management:

In the case of over dosage, treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals, Antifungals for Dermatological use, Antifungals for Topical use, Other Antifungals for Topical use.

ATC Classification: D01A E18

Tolnaftate is a topical antifungal agent

5.2 Pharmacokinetic properties

Not applicable for a topical dosage form.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxytoluene (E321)

Polyethylene - polypropylene glycol monobutyl ether

Ethanol

Butane

Propane

Iso-butane

6.2 Incompatibilities

None stated.

6.3 Shelf life

48 months unopened

6.4 Special precautions for storage

Warnings for the labelling:

Pressurised container: May burst if heated.

Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

Do not spray on open flame or other ignition source.

Pressurised container: Do not pierce or burn, even after use.

Protect from sunlight. Do not expose to temperatures exceeding 50° C / 122° F.

Danger. Extremely Flammable Aerosol (and logo)

6.5 Nature and contents of container

Tinplate aerosol can, epoxy coated internally with valve assembly and overcap. Can sizes: 150ml.

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

Scholl's Wellness Company Limited

1 Arlington Square,
Downshire Way,
Bracknell, Berkshire,
RG12 1WA,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 56058/0002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

24/04/85 / 29/01/99

10 DATE OF REVISION OF THE TEXT

25/07/2025