Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scholl Athlete's Foot Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1.00% w/w

Excipients: Butylated Hydroxytoluene (E321) 0.002% w/w
Chlorocresol 0.1% w/w
Cetostearyl alcohol 7.2% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
Smooth, white, odourless cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Posology:
Adults:Apply to the affected area twice daily or as directed by a doctor. Continue treatment for two weeks after symptoms disappear. Paediatric population: As above for adults.

Method of Administration:
Topical application only. Wash and dry the infected before applying. Wear clean socks or hosiery. Apply liberally.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.
Contraindicated in nail or scalp infections.

4.4 Special warnings and precautions for use

For external use only.
Keep out of eyes.
If irritation or rash continues, use of the product should be discontinued and medical advice should be sought.
If symptoms do not improve within 10 days, discontinue use and consult your doctor. Contains chlorocresol. May cause allergic reactions.
Also contains butylhydroxytolune (E321) and cetostearyl alcohol. Maycause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and muscos membranes.

4.5 Interaction with other medicinal products and other forms of interactions

Not applicable.

4.6 Fertility, 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:
It is unknown whether Tolnaftate and Tolnaftate metabolites are excreted in human milk.

Fertility:
No data on human fertility is available.

4.7 Effects on ability to drive and use machines

This medication has no known effects on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with Tolnaftate are given below, tabulated by system organ class and frequency. Frequencies aredefined as: Verycommon(≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events 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 reactionsafter authorisation of the medicinal product isimportant. It allows continuedmonitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are askedto report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

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 code: D01AE18

Mechanism of action:
Tolnaftate is a well established drug substance which has antifungal properties. Tolnaftate, a tolcyclate antifungal, is a thiocarbamate derivative that inhibits sterol synthesis at the level of squalene epoxidase in the growing cells.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Dihydrogen Phosphate Dihydrate
White Soft Paraffin
Cetomacrogol 1000
Cetostearyl Alcohol
Mineral Oil
Butylated Hydroxytoluene (E321)
Purified Water.

6.2 Incompatibilities

Not applicable.

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

Internally epoxy resin lined aluminium tube with integral membrane seal and plastic cap within a cardboard containing 25g cream.

Combined pack: 25g Athlete's Foot Cream and 75g Athlete's Foot Powder. Joined by clear wrapping.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special precautions.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/076/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First date of authorisation: 19 November 1986

Last date of authorisation: 19 November 2006

10 DATE OF REVISION OF THE TEXT

May 2019