

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Scholl Advance Athlete's Foot Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cream contains 10mg/ 1% w/w of terbinafine hydrochloride

Excipients with known effect

Benzyl alcohol 1 % w/w

Stearyl alcohol 4 % w/w

Cetyl alcohol 4 % w/w

For a full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

White homogenous cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of tinea pedis (athlete's foot) caused by *Trichophyton* (e.g. *T.rubrum*, *T.mentagrophytes*, *T.verrucosum*, *T.violaceum*) and *Epidermophyton floccosum*.

4.2 Posology and method of administration

Method of administration

Cutaneous use

Adults and the Elderly

Scholl Advance Athlete's Foot Cream is applied once or twice daily to the affected skin and surrounding area in a thin layer and rubbed in gently. Before application the affected skin areas should be cleansed and dried thoroughly. In the case of intertriginous infections (interdigital) the application may be covered with a gauze strip, especially at night.

Duration of treatment is one week for tinea pedis. Relief of symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after two weeks, the diagnosis should be verified by a physician.

Children

Scholl Advance Athlete's Foot Cream is not recommended for use in children below 16 years due to insufficient data on safety and efficacy. See section 5.1 and 5.2.

4.3 Contraindications

Hypersensitivity to terbinafine or any of the excipients in the cream.

4.4 Special warnings and precautions for use

This product is for external use only. Contact with the eyes, face and mucous membranes should be avoided.

This product contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Contact with skin lesions should be avoided.

This medicine contains 10mg benzyl alcohol in 1g-cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

Discontinue use if irritation occurs.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known drug interactions with terbinafine cream.

4.6 Fertility, Pregnancy and lactation

Foetal toxicity and fertility studies suggest no adverse effects.

There is no clinical experience with terbinafine cream in pregnant women. Therefore, unless the potential benefits outweigh any potential risks, Scholl Advance Athlete's Foot Cream should not be administered during pregnancy.

Terbinafine is excreted in breast milk and therefore breast-feeding mothers should not use Scholl Advance Athlete's Foot Cream.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Adverse events which have been associated with terbinafine hydrochloride are given below, tabulated by system organ class and frequency.

Frequencies are defined as very common $\geq 1/10$; common $\geq 1/100 < 1/10$; uncommon $\geq 1/1000 < 1/100$; rare $\geq 1/10,000 < 1/1000$; very rare $\leq 1/10,000$. 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
Immune System Disorders	Rare	Hypersensitivity ^{1, 2}
Skin and Subcutaneous Tissue Disorders	Uncommon	Pruritus, erythema
	Not known	Skin burning sensation
General Disorders and Administration Site Conditions	Uncommon	Stinging
	Not known	Application site irritation ²

Description of selected Adverse Reactions

¹ Hypersensitivity reactions include rash or urticaria.

² Treatment has to be rarely discontinued for allergic reactions at the site of application. However if hypersensitivity reactions occur treatment must be discontinued.

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

Topical terbinafine undergoes poor systemic absorption so overdose is unlikely.

No adverse events in relation to ingestion of terbinafine cream have been reported to date. Adverse reactions similar to those possible after oral administration of terbinafine tablets (e.g. headache, nausea, dizziness and upper gastrointestinal complaints) may occur following accidental ingestion of the cream.

Management

Treatment should be supportive and symptomatic. If accidentally ingested use of activated charcoal should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antifungals for topical use

ATC code: D01A E15

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations, terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi.

The treatment effect of terbinafine is long-lasting: Less than 10% of patients suffering from tinea pedis and treated with terbinafine 1% cream for one week experienced a relapse or re-infection within three months after start of treatment.

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane.

The enzyme squalene epoxidase is not linked to the cytochrome P450 system. Terbinafine does not influence the metabolism of hormones or other drug substances.

5.2 Pharmacokinetic properties

Less than 5% of the dose is absorbed after topical application to humans; systemic exposure is therefore very slight.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide

Benzyl alcohol

Sorbitan stearate

Cetyl palmitate

Cetyl alcohol

Stearyl alcohol

Polysorbate 60

Isopropyl myristate

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 2 Years

Opened: 2 Weeks

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium tube with tamper-evident membrane seal, internal lacquer coating and HDPE screw cap containing 7.5g or 15g of cream.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

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 56058/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/10/2017

10 DATE OF REVISION OF THE TEXT

22/07/2025