SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lamisil AT 1% Cream
Boots Athlete's Foot 1%w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Terbinafine hydrochloride 1% w/w

Excipients with known effect

Each gram of cream contains 40mg cetyl alcohol, 40mg stearyl alcohol and 10mg benzyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults and children over 16 years of age

Lamisil AT 1% Cream is applied once daily.

Duration and frequency of treatment

Duration of treatment is one week for tinea pedis and tinea cruris. Relief of clinical 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.

Dosing in special populations:

Paediatric population

The experience with topical Lamisil AT 1% Cream in children is still limited and its use in children under 16 years cannot therefore be recommended.

Elderly patients

There is no evidence to suggest that elderly patients require different dosages or experience side-effects different to those of younger patients.

Method of administration

For cutaneous use.
The affected area should be cleaned and dried thoroughly before application of Lamisil AT 1% Cream. The cream should be applied to the affected skin and surrounding area in a thin layer and rubbed in lightly. In the case of intertriginous infections (interdigital, intergluteal, inguinal) the application may be covered with a gauze strip, especially at night.

4.3 Contraindications

Hypersensitivity to terbinafine or to any of the excipients contained in the cream, listed in section 6.1.

4.4 Special warnings and precautions for use

Lamisil AT 1% cream is for external use only.
Should be used with caution in patients with lesions where alcohol could be irritating.
Should not be used on the face.
Contact with the eyes should be avoided. May be irritating to the eyes. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.
Should be kept out of the sight and reach of children.
This medicine contains 36 mg benzyl alcohol in each daily dosage which is equivalent to 10 mg/g. Benzyl alcohol may cause allergic reactions.
Lamisil AT 1% Cream contains cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

There are no known drug interactions with Lamisil AT 1% Cream.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Foetal toxicity and fertility studies in animals suggest no adverse effects (see section 5.3).

There is no clinical experience with Lamisil AT 1% Cream in pregnant women. Lamisil AT 1% Cream should not be used during pregnancy, unless clearly necessay.

Lactation

Terbinafine is excreted in breast milk. Therefore mothers should not use Lamisil AT 1% Cream whilst breast-feeding.

Infants must not be allowed to come into contact with any treated skin, including the breast.

Fertility

No effects of terbinafine on fertility have been seen in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

Lamisil AT 1% Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Local symptoms such as pruritis, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema and scab may occur at the site of application.

These minor symptoms must be distinguished from hypersensitivity reactions such as widespread pruritis, rash, bullous eruptions and hives, which are reported in sporadic cases but require discontinuation.

In case of accidental contact with the eyes, terbinafine hydrochloride may be irritating to the eyes.

In rare cases the underlying fungal infection may be aggravated.

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), or not known (can not to be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Immune system disorders

Frequency not known: Hypersensitivity

Eye disorders

Rare: Eye irritation

Skin and subcutaneous tissue disorders

Common: Skin exfoliation, pruritus

Uncommon: Skin lesion, scab, skin disorder, pigmentation disorder, erythema, skin burning sensation

Rare: Dry skin, dermatitis contact, eczema

Frequency not known: Rash
General disorders and administration site conditions
Uncommon: Pain, application site pain, application site irritation

Rare: Condition aggravated

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

The low systemic absorption of topical terbinafine renders overdosage extremely unlikely.

Accidental ingestion of one 30g tube of Lamisil AT 1% Cream, which contains 300mg terbinafine hydrochloride is comparable to ingestion of one Lamisil 250mg tablet (adult oral unit dose).

Should a larger amount of Lamisil AT 1% Cream be inadvertantly ingested, adverse effects similar to those observed with an overdosage of Lamisil tablets are to be expected. These include headache, nausea, epigastric pain and dizziness.

If accidentally ingested, the recommended treatment of overdosage consists of eliminating the active substance, primarily by administration of activated charcoal and giving symptomatic therapy if needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

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 P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

Terbinafine provides long-lasting protection. More than 90% of patients with interdigital tinea pedis (athlete's foot) treated with Terbinafine 1 % cream for one week show no mycological evidence of relapse or re-infection by three months after start of treatment. No such data on tinea cruris are available.

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

In long-term studies (up to 1 year) in rats and dogs no marked toxic effects were seen in either species up to oral doses of about 100 mg/kg a day. At high oral doses, the liver and possibly also the kidneys were identified as potential target organs.

In a two-year oral carcinogenicity study in mice, no neoplastic or other abnormal mg/kg a day. In a two-year oral carcinogenicity study in rats at the highest dose level,

69 mg/kg a day, an increased incidence of liver tumours was observed in males. The changes, which may be associated with peroxisome proliferation, have been shown to be species-specific since they were not seen in the carcinogenicity study in mice or in other studies in mice, dogs or monkeys.

During the studies of high dose oral terbinafine in monkeys, refractile irregularities were observed in the retina at the higher doses (non-toxic effect level was 50 mg/kg). These irregularities were associated with the presence of a terbinafine metabolite in ocular tissue and disappeared after drug discontinuation. They were not associated with histological changes.

A standard battery of in vitro and in vivo genotoxicity tests revealed no evidence of a mutagenic or clastogenic potential for the drug.

No adverse effects on fertility or other reproduction parameters were observed in studies in rats or rabbits.

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

None known.

6.3 Shelf life

Aluminium tube: 3 years
Polypropylene dispenser: 3 years

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Aluminium tube with membrane, with an interior coating of phenol-epoxy based lacquer, closed with a polypropylene cap, or laminated tube (low density polyethylene, aluminium, low density polyethylene) with a high density polyethylene shoulder, sealed with an aluminium/ethylene multilayer copolymer peel-off and closed with a polypropylene cap with built-in point to pierce the peel off, containing 7 g, 7.5 g, 10 g, or 15 g Lamisil AT 1% Cream.

Polypropylene dispenser tube with polypropylene screw-cap closure containing 7 g, 7.5 g, 10 g, or 15 g LAMISIL AT.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Karo Healthcare AB
Box 16184
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8 MARKETING AUTHORISATION NUMBER(S)

PL 50567/0018

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/02/2009

10 DATE OF REVISION OF THE TEXT

29/02/2024