Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamisil 1% w/w cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Terbinafine hydrochloride 1% w/w.

Excipients with known effects: Each gram of cream contains 40mg cetyl alcohol, 40mg stearyl alcohol and 10mg benzyl alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White, smooth to almost smooth, glossy cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fungal infections of the skin caused by *Trichophyton* (e.g. *T.rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis* and *Epidermophyton floccosum*.
Yeast infections of the skin, principally those caused by the genus *Candida* (e.g. *C.albicans*).

Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

4.2 Posology and method of administration

LAMISIL can be applied once or twice daily depending on the indication.

Duration and frequency of treatment

The likely duration of treatments are as follows:

Tineapedis: Once a day for 1 week
Tineacorporis, cruris: Once a day for 1 week
Cutaneous candidiasis: Once or twice a day for 1 to 2 weeks
Pityriasisversicolor: Once or twice a day for 2 weeks

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.

Dosing in special populations:

Paediatric population
The experience with topical LAMISIL in children is still limited and its use 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.

Before first use, the sealing membrane of the tube must be removed or pierced using the spike in the screw cap. Cleanse and dry the affected areas thoroughly before application of LAMISIL. Apply the cream to the affected skin and surrounding area in a thin layer and rub in lightly. In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal) the application may be covered with a gauze strip, especially at night.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

LAMISIL cream is for external use only.

Contact with the eyes should be avoided. May be irritating to the eyes. In case of accidental contact with the eyes, rinse eyes thoroughly with running water.

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

LAMISIL Cream contains 10 mg/g benzyl alcohol. Benzyl alcohol may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known drug interactions with LAMISIL cream.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is no clinical experience with LAMISIL Cream in pregnant women, therefore unless the potential benefits outweigh any possible risks, LAMISIL Cream should not be administered during pregnancy, unless clearly necessary.

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

Breastfeeding
Terbinafine is excreted in breast milk. Therefore mothers should not use LAMISIL Cream whilst breast feeding.
Infants should not be allowed to come into contact with any treated skin, including the breast.

Fertility
No effect 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 Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Local symptoms such as pruritus, 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
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
Not known: Rash

General disorders and administration site conditions
Uncommon: Pain, application site pain, 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 HPRA Pharmacovigilance, website: www.hpra.ie

4.9 Overdose

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

Accidental ingestion of one 30 g tube of LAMISIL cream, which contains 300 mg terbinafine hydrochloride, is comparable to ingestion of one LAMISIL 250 mg tablet (adult oral unit dose).

Should a larger amount of LAMISIL Cream be inadvertently 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.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal for topical use, ATC code: D01A E15.

Mechanism of action and pharmacodynamic effects
Terbinafine is an allylamine which has a broad spectrum of antifungal activityin fungal infections of the skin caused by dermatophytes such as *Trichophyton* (e.g. *T.rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporumcanis*and *Epidermophytonfloccosum.* At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi.
The activity against yeasts is fungicidal (e.g. *Pityrosporumorbiculare*or *Malassezia furfur)* or fungistatic, depending on the species.

Terbinafine has long lasting action, fewer than 10% of athlete's foot sufferers treated with terbinafine 1% Cream for one week show relapse or re-infection by 3 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 squaleneepoxidase in the fungal cell membrane. The enzyme squaleneepoxidase is not linked to the cytochrome P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

5.2 Pharmacokinetic properties

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

Following 7 days usage of Lamisil Cream, concentrations of terbinafine in excess of those required for fungicidal activity are available in the affected stratum corneum for at least 7 days after treatment cessation.

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 findings attributable to treatment were made up to doses of 130 (males) and 156 (females) 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 tumors 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

Not applicable.

6.3 Shelf life

3 years: Aluminium tube and laminated tube

3 years: Polypropylene dispenser tube

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tube with or without aluminium membrane, closed with a polypropylene screw cap. Laminated aluminium tube with aluminium membrane closed with a polypropylene screw cap. Each tube is in a cardboard box. Pack sizes: 15 g and 30 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Karo Pharma AB
Box 16184
103 24 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA22650/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th July 1993

Date of last renewal: 31st October 2008

10 DATE OF REVISION OF THE TEXT

March 2026