# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Lamisil AT 1% Spray

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

10mg terbinafine hydrochloride per 1g spray solution

Excipients with known effect

Each gram of spray contains 250 mg ethanol and 50 mg propylene glycol

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous spray, solution

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

The treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie (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

Lamisil AT 1% Spray is applied once daily, for one week.

**Duration and frequency of treatment:**
Interdigital type tinea pedis, and tinea cruris: Once a day for one week.

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, a physician should be consulted.

**Dosing in special populations:**
Paediatric population

Not to be used in children under 16 years of age. Experience with Lamisil AT 1% Spray in children is 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 from those in younger patients.

**Method of Administration**

For cutaneous use.

Cleanse and dry the affected areas thoroughly before applying Lamisil AT 1% Spray from a distance of 5 to 10 cm. A sufficient amount of spray solution should be applied to wet the treatment area(s) thoroughly, and to cover the affected skin and surrounding area.

## 4.3 Contraindications

Known hypersensitivity to terbinafine or any of the excipients contained in the spray solution (see section 6.1 List of excipients).

## 4.4 Special warnings and precautions for use

Lamisil AT 1% Spray should be used with caution in patients with lesions where alcohol could be irritating.

Lamisil AT 1% Spray is for external use only. It may be irritating to the eyes. Lamisil AT 1% Spray should not be used on the face.

In case of accidental contact with the eyes, rinse eyes thoroughly with running water.

Avoid inhalation. In case of accidental inhalation, consult a physician if any symptoms develop or persist.

Lamisil AT 1% Spray contains 46.56 mg alcohol (ethanol) in each daily dose which is equivalent to 250 mg/g of 96% ethanol. It may cause burning sensation on damaged skin.

Lamisil AT 1% Spray contains 9.7 mg propylene glycol in each daily dose which is equivalent to 50 mg/g

## 4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions are known with Lamisil AT 1% Spray, however as a precaution it is recommended that other medicinal products are not applied on the treated areas.

## 4.6 Fertility, Pregnancy and lactation

**Pregnancy**
Animal studies did not reveal any teratogenic or embryofoetotoxic potential of terbinafine.

No cases of malformations in humans have been reported with Lamisil to date. There is limited clinical experience in pregnant women. Foetal toxicity studies in animals suggest no adverse effects (see section 5.3).

Lamisil AT 1% Spray should not be used during pregnancy unless clearly necessary.

**Lactation**
Terbinafine is excreted in breast milk. Therefore, mothers should not receive Lamisil AT 1% Spray whilst breast-feeding. Infants must 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 AT 1% Spray 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 pruritus, rash, bullous eruptions and hives, which are reported in sporadic cases and 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 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, 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 the contents of one 30 ml bottle of Lamisil AT1% Spray, solution, 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 AT 1% Spray 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.

In case of accidental oral ingestion, the alcohol content has to be considered. Lamisil AT 1% Spray contains 23.5%w/w alcohol.

Treatment of overdose
If accidentally ingested, the recommended treatment of overdosage consists of eliminating the active substance, 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 D01 A)

Terbinafine is an allylamine, which has a broad spectrum of antifungal activity in fungal infections of the skin caused by dermatophytes such as Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum. At low concentrations terbinafine is fungicidal against dermatophytes and moulds. The activity against yeasts is fungicidal (e.g. Pityrosporum orbiculare or Malassezia furfur) or fungistatic, depending on the species.

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 drugs.

## 5.2 Pharmacokinetic properties

Less than 5% of the dose is absorbed after topical application to humans; systemic exposure is thus 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 100mg/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, 69mg/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 50mg/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

Purified water

Ethanol (23.5% w/w)

Propylene glycol

Cetomacrogol 1000.

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate.

### 6.5 Nature and contents of container

Lamisil AT 1% Spray is available as a white round HDPE bottle with a crimped mouth and spray pump in pack sizes of 15ml and 30ml.

### 6.6 Special precautions for disposal

See 4.2 Posology and method of administration and 4.4 Special warnings and precautions for use.

For manipulation of the spray pump the bottle can be held in the upright or inverted position.

When using Lamisil AT 1% Spray for the first time, the patient will need to depress the actuator a few times (usually up to 3 actuations) before the solution is dispensed.

## 7 MARKETING AUTHORISATION HOLDER

Karo Healthcare AB

Box 16184

103 24 Stockholm

Sweden

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 50567/0014

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

23/10/2006

## 10 DATE OF REVISION OF THE TEXT

29/02/2024