LAMISIL DermGel

Lamisil 1% DermGel

QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of gel contains 10 mg terbinafine base.

Excipient(s): contains butylhydroxytoluene (E321) (0.2 mg/g)

For the full list of excipients, see section List of excipients.

PHARMACEUTICAL FORM

Gel - White to off-white glossy gel.

CLINICAL PARTICULARS

Therapeutic indications

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,* e.g. interdigital type tinea pedis (athlete's foot), tinea cruris (dhobie or jock itch) and tinea corporis (ringworm).

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

Recommended Dose

For cutaneous use only.

Adults and adolescents aged 12 years and over Duration and frequency of treatment

- Interdigital type tinea pedis: Once a day for one week.
- Tinea corporis, tinea cruris: Once a day for one week.
- Pityriasis versicolor: Once a day for one week.

Clinical symptoms usually start to improve within a few days. Irregular use or Premature discontinuation of treatment carries the risk of recurrence.

If there are no signs of improvement within 2 weeks of first starting treatment, patients should see a doctor or pharmacist to verify diagnosis.

Method of administration

Before first use, the sealing membrane of the tube must be pierced using the point incorporated into the screw cap.

The affected area should be cleaned and dried thoroughly before application. The gel should be applied to the affected skin and surrounding area in a thin layer and rubbed in lightly.

In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal), the application may be covered with a gauze, especially at night.

Dosing in special populations

Elderly

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

Children

Not recommended for use in children below 12 years of age due to insufficient data on safety and efficacy.

Contraindications

Hypersensitivity to terbinafine or to any of the excipients (see section List of excipients)

Warnings and Precautions

- Should be used with caution in patients with lesions where alcohol could be irritating.
- Should not be used on *the* face.
- **For external use only.**
- May be irritating to the eyes. In case of accidental contact with the eyes, rinse eyes thoroughly with running water.
- Should be kept out of the sight and reach of children.

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

Information concerning excipients

Lamisil Dermgel contains:

- butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Effects on ability to drive and use machines

Lamisil Dermgel has no influence on the ability to drive and use machines.

Interaction with other medicinal products and other forms of interaction

No drug interactions are known with the topical forms of terbinafine.

Pregnancy

For terbinafine, no clinical data on exposed pregnancies are available. Animal studies do not indicate any harmful effects with respect to pregnancy or the health of the foetus. It is not appropriate to use Lamisil Dermgel during pregnancy unless clearly necessary.

Lactation

Terbinafine is excreted into breast-milk. After topical use, only a low systemic exposure is expected. Terbinafine should only be used in a nursing mother if the expected benefit justifies the risk to the infant. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

Side effects

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 rore* (< 1/10,000), or *not known* (cannot be estimated from available data). Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be rare or very rare. 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.

Symptoms and Treatment of Overdose
The low systemic absorption of topical terbinafine renders overdosage extremely unlikely during cutaneous use.

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

Symptoms/signs of overdose fallowing ingestion of terbinafine may include headache, nausea, epigastric pain and dizziness.

Further management should be as clinically indicated or as recommended by the national poisons centres where available.

In case of accidental oral ingestion, the alcohol content (9.4% w/w) has to be considered.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal for topical use.

ATC Code
ATC code: D01A E15

Mechanism of Action
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 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, moulds and certain dimorphic fungi. The activity against yeasts is fungicidal (e.g. *Malassezia* furfur) or fungistatic, depending on the species.

Pharmacokinetic properties
Absorption
Less than 5% of the dose is absorbed after topical application to humans; systemic bioavailability is therefore very low. A similar dermato-pharmacokinetic profile of cutaneous solution, spray and gel to cream was observed in pharmacokinetic studies.

Distribution
Following application of gel for 7 days,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.

Special Patient Populations
The pharmacokinetics of terbinafine in the stratum corneum is unlikely to be affected in subpopulations. Any effects of sub populations on the systemic pharmacokinetics are also unlikely to be clinically significant due to the very low levels of terbinafine that are found following topical application of terbinafine.

Preclinical safety data
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 and 156 mg/kg a day in males and females respectively. 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 in the rat, 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.

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

PHARMACEUTICAL PARTICULARS
List of excipients

Purified water	Polysorbate 20	Benzyl alcohol
Ethanol 96%	Carbomer	Sodium hydroxide
Isopropyl myristate	Sorbitan laurate	Butylhydroxy toluene

Incompatibilities
Not applicable.

Storage
Do not store above 30°C.

Nature and contents of container
Lamisil DermGel is available in a varnished aluminum tube with or without a membrane (aluminum) and closed with a polypropylene screw cap.
Pack-size(s): 15 g
Not all pack sizes may be marketed.

Special precautions for disposal
No special requirements.

Manufacturer
Haleon CH SARL, Nyon, Switzerland.

Product Registration Holder
Zuellig Pharma Sdn Bhd
No. 15 Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150
Shah Alam, Selangor Darul Ehsan, Malaysia.

MALAYSIAN PACKAGE LEAFLET
Date of revision : September 2024