1. Name of The Medicinal Product

Lamisil Cream

2. Qualitative And Quantitative Composition

Active substance: terbinafine hydrochloride 1% W/W (10mg/g terbinafine hydrochloride).

3. Pharmaceutical Form

Cream
Smooth glossy white cream.

4. Clinical Particulars

4.1 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 *Epidemophyton floccosum*.
Yeast infections of the skin principally those caused by the genus *Candida* (e.g. *Candida albicans*).
Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*).
For the treatment of plantar-type tinea pedis (moccasin-type).

4.2 Posology and Method of Administration

Usual posology
Cleanse and dry the affected skin areas thoroughly before application of Lamisil Cream.

Adults and children over 12 years of age
Apply Lamisil Cream 1-2 times per day, based on indication. Apply the cream to the affected skin and surrounding area in a thin layer and rub-in lightly. In case of intertriginous infection (inframammary, interdigital, internatal, inguinal) the application site may be covered with a gauze strip, especially at night.

Usual treatment regimens
Tinea pedis (interdigital), tinea corporis/cruris: Once per day for 1 week.
Tinea pedis plantaris (moccasin-type): Twice per day for 2 weeks.
Skin candidiasis: 1-2 times per day for 1 week.
Tinea versicolor: 1-2 times per 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 one week, the diagnosis should be verified.
The effectiveness of Lamisil Cream has not been studied in patients with Tinea pedis and concomitant severe Onychomycosis.

Special dosage recommendations

Elderly patients
There is no evidence to suggest that elderly patients require different dosages or experience adverse reactions different from those of younger patients.

Paediatric population
The safety and efficacy of Lamisil Cream in children less than 12 years of age have not been established. Due to limited clinical data, application of Lamisil Cream in children less than 12 years of age is not recommended.

4.3 Contraindications
Hypersensitivity to the active substance terbinafine or to any of the excipients listed in section 6.1 "List of excipients”".

4.4 Special warnings and precautions for use

Lamisil is intended for external use only. Contact with the eyes should be avoided. Eye irritation may occur after accidental contact with the eyes. In case of accidental contact with the eyes, immediately rinse the eye and conjunctival sac thoroughly under running water.
Infants and young children must not come into contact with the treated areas of skin, including the breast.
This medicinal product contains 10 mg benzyl alcohol per 1 gram of cream.

Benzyl alcohol may cause allergic reactions and mild local irritations.

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

4.5 Interaction with other medicinal products and other forms of interaction

No studies on interactions have been conducted with Lamisil Cream. There are no known drug interactions with Lamisil Cream to date.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no controlled studies in pregnant women. Reproductive studies in animals have not shown any risks to foetuses.
When Lamisil cream is applied topically, less than 5% of the applied quantity is absorbed. Lamisil cream should not be used during pregnancy unless clearly necessary.

Breastfeeding
Terbinafine is excreted in breast milk, albeit in small amounts. It is not known whether this small amount may have a negative effect on the child. Lamisil cream should not be used in breastfeeding women. Infants and young children must not come into contact with the treated areas of skin, including the breast.

4.7 Effects on ability to drive and use machines
No relevant studies have been conducted.

4.8 Undesirable effects

Local symptoms such as pruritus, desquamation, pain or irritation, pigmentation disorders, burning sensation, erythema or scab may occur at the application site. These harmless symptoms should be distinguished from hypersensitivity reactions including rash, which have been reported in isolated cases and require immediate discontinuation of treatment

Adverse reactions are listed below by system organ class and frequency as observed during topical application of terbinafine. Frequencies are defined as:
Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000).

Immune system disorders
Very rare: hypersensitivity reactions such as urticaria.
Individual cases: Angioedema, anaphylactic shock.

Eye disorders
Rare: irritations.

Skin and subcutaneous tissue disorders
Common: desquamation, pruritus.
Uncommon: skin lesions, scab, other skin changes, pigmentation disorders, erythema, burning sensation.
Rare: dry skin, contact dermatitis, eczema.
Very rare: rash, papules.

General disorders and administration site conditions
Uncommon: pain or irritation at the application site.
In rare cases, the underlying fungal infection may be aggravated.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

4.9 Overdose

Signs and symptoms
The low systemic absorption of topically administered terbinafine makes overdose very unlikely.
Accidental ingestion of, for example, 2 tubes of Lamisil Cream containing 300 mg terbinafine hydrochloride is comparable to ingestion of one tablet of Lamisil 250 mg (i.e the standard oral dose for adults). If a larger amount of a topical Lamisil formulation has been ingested orally, the expected adverse reactions are similar to those after ingesting an overdose of Lamisil tablets. These include headache, nausea, upper abdominal pain and dizziness.

Treatment of overdose

In case of accidental ingestion, the recommended treatment is elimination of the substance by the administration of activated charcoal, and, if necessary, symptomatic supportive therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antifungal agent for topical use
ATC code: D01AE15

Mechanism of action

Terbinafine is a broad spectrum antifungal agent belonging to the class of allylamines. It has a fungicidal action against dermatophytes, moulds and certain dimorphic fungi. The effect against yeasts is fungicidal or fungistatic, depending on the species. Terbinafine specifically interferes with ergosterol biosynthesis in the fungal cell membrane at an early stage. Inhibition of the enzyme squalene epoxidase results in an ergosterol deficiency and an intracellular accumulation of squalene, which results in fungal cell death, inter alia, due to the disruption of membrane function. Terbinafine inhibits squalene epoxidase in the cell membrane of the fungus. The enzyme squalene epoxidase does not belong to the cytochrome P450 system.
Terbinafine therefore has no effect on the metabolism of hormones or other medicinal products.

Minimum inhibitory concentration in vitro

Fungal genus	µg/ml
Sensitive:	
Trichophyton rubrum	0.003–0.006
T. mentagrophytes	0.003–0.01
T. tonsurans	0.003
T. verrucosum	0.003
T. schönleinii	0.006
Microsporum canis	0.006–0.01
M. versicolor	0.003
M. gypseum	0.006
Epidermophyton floccosum	0.003–0.006
Moderately sensitive:	
Aspergillus fumigatus	0.1–1.56
Sporothrix schenckii	0.1–0.4
Candida albicans:	
Yeast form	25–100
Mycelium form	0.23–0.7
C. parapsilosis	0.8–3.1
Pityrosporum ovale	0.2–0.8
P. orbiculare	0.8

Pharmacodynamic effects

No details.

Clinical efficacy and safety

Lamisil can be recommended as short-term therapy (1-2 weeks depending on the indication). Most patients with interdigital mycosis, had no recurrence 2 months after one week of Lamisil cream treatment.
In two double-blind, vehicle controlled studies (follow-up time 8 weeks) with a total of n=193 patients, the efficacy of Lamisil cream was also demonstrated in plantar mycosis (known as "moccasin tinea pedis"). In these studies, after twice-daily application over two weeks, no pathogens were detectable in the swab in around 70% of patients. Patients with concomitant severe onychomycosis were not included in this study. For the other topical dosage forms, efficacy in this indication has not been studied.

5.2 Pharmacokinetic properties

Absorption

Less than 5% of the dose is absorbed after topical application to humans. Systemic exposure is therefore very slight after local topical administration.

Distribution

After topical administration terbinafine penetrates into the skin and accumulates in the stratum corneum. After topical administration for 7 days, terbinafine is measurable in the stratum corneum for further a 7-days in fungicidal concentration.

Metabolism

No details.

Elimination

No details.

5.3 Preclinical safety data

Reproductive toxicity
No adverse effects on fertility or other reproductive parameters were observed in studies in rats or rabbits.

Mutagenicity
A standard set of in vitro and in vivo genotoxicity tests have not shown evidence of a mutagenic or clastogenic potential.

Carcinogenicity
In a 2-year oral carcinogenicity study in mice, no neoplastic or other abnormal findings were observed when treated with doses up to 130 mg/kg (males) and 156 mg/kg (females) per day. In a 2-year oral carcinogenicity study in rats at the highest dose level of 69 mg/kg per day, an increased incidence of liver tumours was observed in male animals. These changes, which may be associated with the proliferation of peroxisomes, are to be considered species-specific as they were not observed in the carcinogenicity study in mice or in other studies in mice, dogs and monkeys.

6. Pharmaceutical Particulars

6.1 List of excipients
isopropyl myristate, polysorbate 60, cetyl alcohol, stearyl alcohol, cetyl palmitate, sorbitan stearate, benzyl alcohol, sodium hydroxide, purified water

6.2 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.3 Special precautions for storage
Special storage instructions
Store below 30°C.
Keep out of the reach of children.

6.4 Nature and contents of container
Lamisil Cream is a white cream packaged in a varnished laminated tube with or without a membrane (aluminum) and closed with polypropylene screw cap. Pack sizes 15 g and 30 g. Not all pack sizes may be marketed.

7. License Holder
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