LAMISIL
CREAM 10MG/G TUBE 15G
MY Artwork

karo healthcare

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Leading	7pt
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Smallest Text Size	6pt
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Technical (Non Printing).

Cutter Guides

OVERPRINT PREVIEW **NO**

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LAMISIL Cream

Lamisil Cream 1%

QUALITATIVE AND QUANTITATIVE COMPOSITION
One gram of Lamisil 1% Cream contains 10 mg terbinafine hydrocholoride, equivalent to 8.8 mg of terbinafine base.

Excipient(s): contains cetyl alcohol (40 mg/g) and stearyl alcohol (40mg/g).

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

PHARMACEUTICAL FORM
Cream - White, smooth, or almost smooth, glossy cream.

CLINICAL PARTICULARS
Therapeutic indications
Fungal infections of the skin caused by dermatophytes such as *Trichophyton* (e.g. *I rubrum, I mentagrophytes, I verrucosum, I vio/aceum), Microsporum canis and Epidermophyton1/occosum*, e.g. tinea pedis (athlete›s foot), tinea cruris (dhobie uock) itch) and tinea corporis (ringworm).

Yeasts infections of the skin, principally those caused by the genus Candida (e.g.*Candida albicam*).

Pityriasis (tinea) versicolor due to *Pityrosporum orbicu/are* (also known as *Ma/assezia furfui*).

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.
- Plantar type tinea pedis: Twice a day for two weeks.
- Tinea corporis, tineacruris: Once a day for one week.
- Cutaneous candidiasis: Once or twice a day for one to two weeks.
- Pityriasis versicolor: Once or twice a day for two weeks.

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 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 (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 listed in section List of excipients.

Warnings and Precautions
- For external use only. - If applied to face keep away from eyes.
- 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 Cream contains:
- cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Effects on ability to drive and use machines
Lamisil Cream 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 for use Lamisil Cream 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 rare* (< 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: Ory 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 cream, which contains 300 mg terbinafine base, is comparable to ingestion of one Terbinafine 250 mg tablet (adult oral unit dose).

Symptoms/signs of overdose following 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: D01AE15

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 futfui*') 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 cream for 7 days, concentrations of terbinafine in excess of those required for fungicidal activity are available in the affected stratum comeum 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
Sodium hydroxide
Benzyl alcohol
Sorbitan monostearate
Cetyl palmitate
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Isopropyl myristate

Incompatibilities
Not applicable.

Storage
Do not store above 30°C.

Nature and contents of container
Pack-size(s): 7.5g , 15g
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
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