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: Each gram of cream contains 40mg cetyl alcohol and 40mg stearyl alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Greece
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. 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.

The likely durations of treatment are as follows:

Tinea pedis:	1 week
Tinea corporis, cruris:	1 to 2 weeks
Cutaneous candidiasis:	1 to 2 weeks
Pityriasis versicolor:	2 weeks

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

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.

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

Children
The experience with topical LAMISIL in children is still limited and its use cannot therefore be recommended.

4.3 Contraindications

Hypersensitivity to terbinafine or any of the excipients contained in the cream.

4.4 Special warnings and precautions for use

LAMISIL cream is for external use only. Contact with the eyes should be avoided.

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

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

Foetal toxicity and fertility studies in animals suggest no adverse effects.

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

Terbinafine is excreted in breast milk and therefore mothers should not receive LAMISIL whilst breast feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Redness, itching or stinging occasionally occur at the site of application; however, treatment rarely has to be discontinued for this reason. This must be distinguished from allergic reactions which are rare but require discontinuation.

4.9 Overdose

No case of ingestion of LAMISIL cream has been reported to the Company, however if accidental ingestion of LAMISIL cream occurs, an appropriate method of gastric emptying may be used if considered appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity against yeasts is fungicidal or fungistatic depending on the species.

5.2 Pharmacokinetic properties

Terbinafine interferes specifically with fungal sterol biosynthesis at an early stage. 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide
Benzyl alcohol
Sorbitan monostearate
Cetyl palmitate
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Isopropyl myristate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30^{o}C. Do not refrigerate.

6.5 Nature and contents of container

Outer carton containing an aluminium tube with screw-cap.

Pack size: 15g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/029/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd September 2011.

10 DATE OF REVISION OF THE TEXT