Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamisil 1% w/w cutaneous spray, powder, pressurised container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cutaneous spray, powder contains 10 mg terbinafine hydrochloride (1%w/w).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, powder, pressurised container.

Off-white liquid aerosol suspension delivering an off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fungal infections of the skin caused by dermatophytes: interdigital-type tinea pedis and tinea cruris.

4.2 Posology and method of administration

Cutaneous use

Adults
Lamisil spray powder is applied once or twice daily, depending on the indication. Cleanse and dry the affected areas thoroughly before applying Lamisil spray powder. The container should be held 10-15 cm from the skin and a sufficient amount of product be sprayed to cover the affected skin and surrounding area.

Duration and frequency of treatment:

Interdigital type tinea pedis:	Twice a day for 1 week
Tinea cruris:	Once a day for 1 week

Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence.

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

Use of Lamisil spray powder in paediatric patients
Lamisil spray powder is not recommended for use in paediatric patients due to insufficient data on safety and efficacy.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients (see section 6.1).

4.4 Special warnings and precautions for use

Lamisil spray powder should be used with caution in patients with lesions where alcohol could be irritating.

Lamisil spray powder is for external use only. It may be irritating to the eyes. It should not be used on the face.

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

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

Lamisil spray powder should be kept out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions are known with Lamisil spray powder.
No data are available on the concomitant administration of Lamisil Spray Powder and other topical medicines, therefore other topical treatments must not be used with Lamisil Spray Powder at the same site.

4.6 Fertility, pregnancy and lactation

Animal studies did not reveal any teratogenic or embryofoetotoxic potential of terbinafine. No cases of malformations in humans have been reported with terbinafine to date. However, since clinical experience in pregnant women is very limited, Lamisil spray powder should be used only if clearly indicated during pregnancy.

Terbinafine is excreted in breast milk and therefore mothers should not receive Lamisil spray powder whilst breast-feeding. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

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 spray powder has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Redness, itching, stinging or skin dryness may occur at the site application; however, treatment rarely has to be discontinued for this reason. These harmless symptoms must be distinguished from allergic reactions such as pruritus, rash, bullous eruptions and hives which are very rare but require discontinuation.

4.9 Overdose

The low systemic absorption of topical terbinafine spray powder renders overdosage extremely unlikely. Accidental ingestion of the contents of one can of 15 g Lamisil spray powder concentrate, which contains 150 mg terbinafine hydrochloride, is comparable to half of a Lamisil 250 mg tablet (adult oral unit dose).

Should a larger amount of Lamisil spray powder 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. The alcohol content (57.8% of the concentrate) of the spray powder has to be taken into account.

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: Other antifungals for topical use (ATC code D01A E15).

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 substances.

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 100 mg/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, 69 mg/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 50 mg/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

Ethanol anhydrous
Aluminium starch octenyl succinate
Isopropyl myristate
Sorbitan oleate
Stearalkonium hectorite
Propylene carbonate
Sodium hydrogen carbonate
Isobutane (propellant)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

Caution Extremely flammable.

Pressurised container. Protect from sunlight and do not expose to temperatures above +50°C. Do not pierce or burn, even after use.

6.5 Nature and contents of container

Pressurised aluminium can crimped with a spray valve. Pack size: 15 g.

6.6 Special precautions for disposal and other handling

There are no specific instructions for use/handling

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 030/44/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th February 2012

10 DATE OF REVISION OF THE TEXT