Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lanafine 1% (w/w) Cream
Terbinafine hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

10 mg terbinafine hydrochloride (equivalent to 8.89 mg terbinafine) in 1 g cream.

Excipients: also contains cetyl alcohol and cetostearyl alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
White or almost white cream, with slight almond odour.

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* (eg. *C. albicans*).

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

4.2 Posology and method of administration

Terbinafine cream can be applied once or twice daily. Cleanse and dry the affected areas thoroughly before application of Terbinafine cream. 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 corporis, cruris: 1 to 2 weeks
Tinea pedis: 1 week
Cutaneous candidiasis: 2 weeks
Pityriasis versicolor: 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 two weeks, the diagnosis should be verified.

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

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.

Method of administration
Via the topical route.

4.3 Contraindications

Known hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings and precautions for use

Terbinafine cream is for external use only. Contact with the eyes should be avoided. If it gets into the eyes accidentally, the eyes should be washed with plenty of water and the patient should turn to an ophthalmologist if necessary.

Terbinafine cream contains cetyl alcohol and cetostearyl 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 Terbinafine cream.

4.6 Fertility, pregnancy and lactation

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

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

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

4.7 Effects on ability to drive and use machines

There are no data available that terbinafine would affect driving ability or any other activity requiring concentration.

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

Terbinafine cream is for external use only. If accidental ingestion of the cream occurs, appropriate method of gastric lavage can be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antifungals for topical use
ATC code: D01A E15

Terbinafine is an antimycotic with a broad-spectrum of anti-fungal activity belonging to the allylamine group. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity against yeasts, e.g. Candida species is fungicidal or fungistatic depending on the species.

Terbinafine interferes with fungal sterol biosynthesis by the inhibition of squalene epoxidase in the fungal cell membrane, which leads to an intracellular accumulation of squalene, resulting in fungal cell death.

5.2 Pharmacokinetic properties

Less than 5% of the dose is absorbed after topical application; systemic exposure is therefore very slight.

Terbinafine does not influence the cytochrome P-450 enzyme system and the metabolism of hormones and other drugs depending on cytochrome P-450 system.

5.3 Preclinical safety data

None known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide
Benzyl alcohol
Sorbitum stearate
Cetyl palmitate
Cetyl alcohol
Cetostearyl alcohol
Polysorbate 60
Isopropyl myristate
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

4 years
Once opened: 6 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium tube closed by polyethylene cap. The tubes are containing 7.5 g, 15 g or 30 g cream.

Not all packs may be marketed.

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 MARKETING AUTHORISATION HOLDER

Niche Generics Limited,
1 The Cam Centre,
Wilbury Way,
Hitchin Hertfordshire SG4 OTW,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 1063/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 November 2005
Date of last renewal: 11 November 2010

10 DATE OF REVISION OF THE TEXT

October 2011