Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Terbinafine 10 mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of cream contains: terbinafine hydrochloride 10 mg.

Excipients with known effect: stearyl alcohol 40 mg/g and cetyl alcohol 40 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

White cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of fungal skin infections caused by dermatophytes such as *Trichophyton* (e.g. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis* and *Epidermophyton floccosum*.

Treatment of skin infections due to yeasts, mainly those caused by the *Candida* genus (e.g. *Candida albicans*).

Treatment of pityriasis (tinea) versicolor caused by *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

4.2 Posology and method of administration

Method of administration

For cutaneous use.

Adults and children from 12 years of age
Cleanse and dry the affected areas thoroughly before application of Terbinafine 10 mg/g 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.

Posology

The likely frequencies and durations of treatment are as follows:

Tinea pedis:	Once daily for 1 week
Tinea corporis, cruris:	Once daily for 1 week
Cutaneous candidiasis:	Once daily for 1 to 2 weeks
Pityriasis versicolor:	Once to twice daily 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 two weeks the diagnosis should be verified.

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

Paediatric population
The experience with topical Terbinafine 10 mg/g cream in children is still limited and therefore its use cannot be recommended for children under the age of 12.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Terbinafine 10 mg/g cream is for external use only.

Avoid contact with eyes, mucosa or lesions. Should the cream come into contact with one of these areas, rinse with plenty of running water.

This medication contains stearyl alcohol and cetyl alcohol, which can cause local skin irritation (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions between Terbinafine 10 mg/g cream and other medicinal product.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is no clinical experience with terbinafine in pregnant women.

Breastfeeding
Terbinafine is excreted in breast milk. After topical administration only low systemic exposure is anticipated (see section 5.2). Terbinafine 10 mg/g cream should not be administered while breast-feeding unless clearly indicated.

Fertility
Reproductive toxicity studies conducted in animals suggest no adverse effects (see section 5.3). Terbinafine 10 mg/g cream should not be administered during pregnancy unless clearly necessary.

4.7 Effects on ability to drive and use machines

Application of Terbinafine 10 mg/g cream to the skin does not affect the ability to drive or use machines.

4.8 Undesirable effects

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
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)
Not known (cannot be estimated from the available data).

Immune system disorders
Rare: Allergic reactions such as pruritus, rash, dermatitis bullous and urticaria.

Skin and subcutaneous tissue disorders
Redness, rash and an itching or stinging sensation may occur at the application site.
These, however, seldom lead to discontinuation of the treatment. It is important to distinguish basically harmless symptoms from allergic reactions which may require discontinuation of the treatment.

4.9 Overdose

Should terbinafine cream be ingested accidentally, adverse effects similar to those observed with an overdose of tablets containing terbinafine (e.g. headache, nausea, epigastric pain and dizziness) are to be expected.

If accidental ingestion of terbinafine cream occurs an appropriate method of gastric emptying may be used if considered appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antifungals for topical use, ATC code: DO1AE15.

Terbinafine is an allylamine with a broad spectrum of antimycotic activity. It has an antimycotic effect on fungal infections of the skin caused by dermatophytes such as *Trichophyton* (e.g. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis* and *Epdermophyton floccosum.* At low concentrations terbinafine has a fungicidal effect against dermatophytes and moulds. Its activity against yeasts is fungicidal (e.g. *Pityrosporum orbiculare* or *Malassezia furfur*) or fungistatic, depending on the species.

Terbinafine interferes specifically at an early step in fungal sterol biosynthesis. This leads to a lack of ergosterol and to intracellular accumulation of squalene, which leads to death of the fungal cell. Terbinafine acts through inhibition of the enzyme squalene epoxidase in the fungal cell membrane. This enzyme has no relation to the cytochrome P450 system. As far as is known, terbinafine has no effect on the metabolism of other drugs or hormones.

5.2 Pharmacokinetic properties

Absorption
In humans, after topical applications, absorption is less than 5% of the dose; systemic exposure is thus very limited.

Elimination
After 7 days of Terbinafine 10 mg/g cream use, concentrations of terbinafine above those needed for fungicidal activity are observed in the affected stratum corneum for at least 7 days after treatment is discontinued.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure after topical administration indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.
After tube is 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 internally lacquered and sealed with latex, with a perforating screw-on cap.

Pack sizes:
7.5 g tube
15 g tube
30 g tube

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

There are no special requirements.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf.
Reykjavíkurvegur 76-78
220 Hafnarfjordur
Iceland

8 MARKETING AUTHORISATION NUMBER

PA 1380/79/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6 November 2009

Date of last renewal: 28 August 2012

10 DATE OF REVISION OF THE TEXT

March 2013