Summary of Product Characteristics

1. Name of the medicinal product

Norbasil Cream

2. Qualitative and quantitative composition

One gram of cream contains 10 mg Terbinafine hydrochloride equivalent to 8.89 mg of Terbinafine.

Excipients with known effect:

Each gram of cream contains 10 mg benzyl alcohol, 40 mg Cetostearyl alcohol and 40 mg cetyl alcohol.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream

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

4. Clinical particulars

4.1 Therapeutic indications

The treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch/jock itch)

Fungal infections of the skin caused by dermatophytes such as species of Trichophyton (e.g. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis and Epidermophyton floc*cosum.

Infections of the skin caused by *Candida* (e.g. *Candida albicans*).

Pityriasis (tinea) versicolor caused by *Pityrosporum orbiculare* (*Malassezia furfur*).

4.2 Posology and method of administration

Posology

Adults and adolescents (>12 years of age)

Duration and frequency of treatment:

Terbinafine can be applied once or twice daily.

The likely duration of each treatment is as follows:

Tinea pedis: 1 week.

Tinea cruris and Tinea corporis: 1 to 2 weeks.

Cutaneous candida: 2 weeks.

Pityriasis versicolor: 2 weeks.

Relief of symptoms is usually obtained within a few days.

Irregular use or an inadequate treatment period increases the risk of the symptoms returning. If no improvement is obtained after 2 weeks, the diagnosis should be re-evaluated.

Elderly

There has been nothing to indicate that elderly patients require a different dosage or have a side effects profile different from younger patients.

Paediatric population

Terbinafine 1 % Cream is not recommended for children below 12 years of age due to insufficient data on safety. The experience in children is limited.

Method of administration

For cutaneous use.

The skin should be clean and dry. The cream should be applied in a thin layer on and around the affected skin and rubbed in gently. In cases of reddened and weeping infection (under the breasts,

between the fingers, buttocks or in the groin) the skin may be covered with a sterile compress after application of the cream, especially at night.

4.3 Contraindications

Hypersensitivity to the active substance, Terbinafine, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Terbinafine 1 % Cream is for external use only.

Terbinafine 1 % Cream may be irritating to the eyes. Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse eyes thoroughly with running water.

Terbinafine cream should be kept out of the reach of children.

In the event of allergic reaction, the cream should be removed and the treatment interrupted.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Candidiasis: It is not recommended to use acid pH soap. This provides favourable growth conditions for *Candida* spp.

Excipients

This medicine contains 10 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. This medicine also 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

No drug interactions are known with the topical forms of Terbinafine.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no clinical experience with Terbinafine in pregnant women. Foetal toxicity studies conducted in animals suggest no adverse effects (see section 5.3). Terbinafine 1 % Cream should not be used during pregnancy unless clearly necessary.

Breast-feeding

Terbinafine is excreted into breast-milk. After topical use, only a low systemic exposure is expected (see section 5.2). Terbinafine 1 % Cream should not be used during breast-feeding. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

Fertility

No effects of Terbinafine on fertility have been seen in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

Terbinafine 1 % Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Local symptoms such as pruritus, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema, scab, etc. may occur at the site of application.

These harmless symptoms must be distinguished from hypersensitivity reactions including rash, which are reported in sporadic cases and require discontinuation of therapy.

In case of accidental contact with the eyes Terbinafine may be irritating to the eyes.

In rare cases the underlying fungal infection may be aggravated.

Adverse reactions are listed below by system organ class and the 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), not known (cannot be estimated from the available data). 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: Dry skin, dermatitis contact, eczema

Not known: Rash*

General disorders and administration site conditions

Uncommon: Pain, application site pain, application site irritation

Rare: Condition aggravated

* Based on post-marketing experience.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

The low systemic absorption of topical Terbinafine renders over dose extremely unlikely.

Symptoms

Accidental ingestion of one 30 g tube of Terbinafine cream, which contains 300 mg Terbinafine hydrochloride, is comparable to ingestion of one Terbinafine 250 mg tablet (adult oral unit dose).

Should a larger amount of Terbinafine cream be inadvertently ingested, adverse effects similar to those observed with an over dose of Terbinafine tablets are to be expected. These include headache, nausea, epigastric pain and dizziness.

Treatment

If accidentally ingested, the recommended treatment of over dose consists of eliminating the active substance, primarily by the administration of activated charcoal, and giving symptomatic supportive therapy if needed.

5. Pharmacological properties

6. Pharmaceutical particulars

6.1 List of excipients
Sodium hydroxide
Benzyl alcohol
Sorbitan monostearate
Cetyl palmitate
Cetyl alcohol
Cetostearyl alcohol
Polysorbate 60
Isopropyl myristate
Purified water.
6.2 Incompatibilities
Not applicable.
6.3 Shelf life
4 years
Shelf life after opening 28 days
6.4 Special precautions for storage
Store in original container after first opening.
Do not freeze.
Keep the tube tightly closed.
6.5 Nature and contents of container
Collapsible aluminum tube with a polyethylene screw cap in pack sizes of 7.5 g, 15 g or 30 g.
Not all pack sizes may be marketed.
6.6 Special precautions for disposal and other handling
Not applicable
7. Marketing authorization holder
Marine Lifesciences, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom
8. Marketing authorization number(s)
NA
9. Date of first authorization/renewal of the authorization
10/02/2010
10. Date of revision of the text
04/2019

M/S Marine Lifesciences
Address
Plot no. 30, HPSIDC Baddi, Solan 173205, H.P.
WWW
NA
Telephone
01795-605005
Fax
N/A

Medical Information Direct Line

09216871933

Medical Information e-mail

marine.lifesciences1@gmail.com

Customer Care direct line

09216871933

Medical Information Fax

Not applicable

Stock Availability