PACKAGE INSERT TEMPLATE FOR TERBINAFINE CREAM / GEL

Brand or Product Name

[Product name] Cream 1% w/w
[Product name] Gel 1% w/w

Name and Strength of Active Substance(s)

Terbinafine hydrochloride 1% w/w

Product Description

[Visual description of the appearance of the product (eg colour, odour, viscosity, texture etc)]
eg White, smooth glossy cream with a characteristic odour
Homogeneous, white to off-white glossy gel

Pharmacodynamics

Terbinafine is an allylamine which has a broad spectrum of antifungal activity in fungal infections of the skin. It's action being fungicidal against dermatophytes, moulds and certain dimorphous fungi. It has a fungicidal or fungistatic action on yeasts depending on the species involved.
Terbinafine interferes with fungal ergosterol biosynthesis at an early stage. This leads to a deficiency in ergosterol and to intracellular accumulation of squalene, resulting in fungal cell death.
Terbinafine acts by inhibiting squalene epoxidase in the fungal cell membrane. The squalene epoxidase is not dependent on the cytochrome P450 system. Terbinafine does not have any influence on the metabolism of hormones or of other medicines.

Pharmacokinetics

Less than 5% of the dose is absorbed after topical application in humans; systemic exposure is thus very slight. Biotransformation results in metabolites with no antifungal activity, which is excreted predominantly in the urine and the faeces. The elimination half life is 17 hours. There is no evidence of accumulation. At the level of the stratum corneum, fungicidal concentrations of terbinafine can be measured up to 7 days after the last administration.

Indication

•Fungal infections of the skin: Dermatophytes such as *Trichophyton* (e.g. *T.rubrum. T.mentagrophytes, T.verrucosum, T.violaceum*), *Microsporum canis* and *Epidermophyton floccosum*;
Example of infections; athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)

•Yeast infections of the skin: *Candida* (e.g. *Candida albicans*);

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

Recommended Dosage

Adults and children from 12 years:
Cleanse and dry the affected areas thoroughly before application

Cream/Gel: Apply a thin layer on the affected skin and surrounding areas by rubbing in gently. Cream can be applied once or twice daily. The likely durations of treatment are as follows:

Tinea corporis, cruris: 1 to 2 weeks
Tinea pedis: Toes, twice daily for 1 week, on the bottom or sides of the foot for 2 weeks
Cutaneous candidiasis: 2 weeks
Pityriasis versicolor: 2 weeks

In cases of intertriginous infections (submammary, interdigital, intergluteal, inguinal), a gauze can be used, especially for applications in the evening.

Relief of clinical symptoms usually occurs within a few days. Regular application is essential for successful treatment. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after one week, the diagnosis should be verified.

Children
The experience with topical terbinafine 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.

Mode of Administration

Topical

Contraindications

Hypersenitivity to terbinafine hydrochloride or any of the excipients contained in the preparation.

Warnings and Precautions

- For external use only.
- Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.
- In the event of skin lesions, use with care if the preparation contains alcohol which can irritate.

Effects on Ability to Drive and Use Machines
Unlikely to impair a patient's ability to drive or use machinery

Interactions with Other Medicaments

There are no known drug interactions with topical applications of terbinafine hydrochloride.

Statement on Usage During Pregnancy and Lactation

There is no clinical experience in pregnant women; therefore, unless the potential benefits outweigh any potential risks, it should not be administered during pregnancy.
Terbinafine is excreted in breast milk and although the amount involved is small, mothers should not receive it whilst breast-feeding. Infants should also not be allowed to come into contact with any treated skin, including the breast.

Adverse Effects / Undesirable Effects

Erythema (redness), pruritus (itching) or stinging (burning sensation) occasionally occurs at the site of application; however, treatment rarely has to be discontinued for this reason.
This must be distinguished from allergic reactions which are very rare but require discontinuation.

Overdose and Treatment

No case of overdosage has been reported so far. However, should a large amount of the preparation be inadvertently ingested, adverse effects similar to those observed with an overdosage of a tablet form of terbinafine are to be expected. These include headache, nausea, vomiting, epigastric pain and dizziness.
In case of accidental oral ingestion, gastric lavage and / or symptomatic supportive treatment should be performed as soon as possible.

Storage Conditions
[e.g. Store below… ℃]

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]