SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Terbinafine Cream 1% w/w

2. Qualitative and quantitative composition

Composition:

Terbinafine Hydrochloride USP…….1% w/w

For a list of excipients, see section 6.1.

3. Pharmaceutical form

Cream

White colored cream.

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 (e.g. C.albicans).*

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

4.2 Posology and method of administration

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including older people)

Terbinafine Hydrochloride Cream 1% w/w may be applied 1-2 times daily. The recommended duration and frequency of treatment will depend upon the type and area of infection:

Tinea pedis (Athlet's foot): 1 week

Tinea corporis, cruris: 1 to 2 weeks

Cutaneous candidiasis: 1 to 2 weeks

Pityriasis versicolor: 2 weeks

Infection usually appears to improve within a few days of starting to use the cream. It is important that you use the cream. It is important that you use the cream regularly even if the infection has improved. If you see no improvement in your skin condition after 2 week, talk to your doctor.

Direction of use.

Cleanse and dry the affected areas thoroughly and wash your hands. Treatment can be helped by keeping the affected areas clean by regular washing and careful drying with your own clean towels and cloths, and not rubbing or scratching the skin.

4.3 Contraindications

Hypersensitivity to terbinafine or any of the excipients contained in the cream.

4.4 Special warnings and precautions for use

Terbinafine cream is for external use only. Contact with the eyes should be avoided.

This product contains cetyl alcohol and stearyl 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 in pregnant women, therefore unless the potential benefits outweigh any potential risks Terbinafine should not be administered during pregnancy.

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

4.7 Effects on ability to drive and use machines

None known.

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

No case of ingestion of Terbinafine cream has been reported to the Company, however 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

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity against yeasts is fungicidal or fungistatic depending on the species.

5.2 Pharmacokinetic properties

Terbinafine interferes specifically with fungal sterol biosynthesis at an early stage. 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 P-450 system.

Terbinafine does not influence the metabolism of hormones or other drugs.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Light Liquid Parafin
White Soft Paraffin
Cetostearyl Alcohol
Cetomacrogol 1000
Chlorocresol
Propylene Glycol
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature not exceeding 25° C. Protect from light.

6.5 Nature and contents of container

30 gm printed lami tube & sealed with white colored plastic cap having ceramic print packed in a printed box with leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

NA

8. Marketing authorisation number(s)

NA

9. Date of first authorisation/renewal of the authorization

NA

10. Date of revision of the text

NA

11. Manufactured by:

KWALITY PHARMACEUTICALS LTD.

Village Nag Kalan, Majitha Road,

Amritsar-143601 (INDIA)