Summary of Product Characteristics

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

AKRISIL (Terbinafine Hydrochloride Cream 1%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1.QUALITATIVE DECLARATION

Terbinafine Hydrochloride USP 1% w/w

2.2.QUANTITATIVE DECLARATION

Terbinafine Hydrochloride USP 1% w/w
Cream Base q.s

3. PHARNACEUTICAL FORM

Cream

White Colour homogeneous cream free from firm particulate matter.

4. CLINICAL PARTICULARS

4.1.THERAPEUTIC INDICATION

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*), *Microsporumcanis and Epidermophytonfloc*cosum.

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

Pityriasis (tinea) versicolor caused by *Pityrosporumorbiculare* (*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 & PRECAUTIONS FOR USE

Terbinafine 1 % Cream cream is for external use only.

Terbinafine 1 % Cream 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.

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.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 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.

4.7.EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No harmful effects have been observed

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.

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

5.1.PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antifungal for topical use (ATC code D01A E15)

Terbinafine is an allylamine that has 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*)*, Microsporumcanis* and *Epdermophytonfloccosum.* At low concentrations terbinafine has a fungicidal effect against dermatophytes and moulds. Its activity against yeasts is fungicidal (e.g. *Pityrosporumorbiculare* or *Malassezia furfur*) or fungistatic, depending on the species.

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. 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.

5.2.PHARMACOKINETIC PROPERTIES

Less than 5% of the dose is absorbed after topical application to humans: systemic exposure is thus very low.

5.3. PRE-CLINICAL SAFETY DATA:

In long-term studies (up to 1 year) in rats and dogs no marked toxic effects were seen in either species up to oral doses of about 100 mg/kg a day. At high oral doses, the liver and possibly also the kidneys were identified as potential target organs.

In a two-year oral carcinogenicity study in mice, no neoplastic or other abnormal findings attributable to treatment were made up to doses of 130 (males) and 156 (females) mg/kg a day. In a two-year oral carcinogenicity study in rats at the highest dose level, 69 mg/kg a day, an increased incidence of liver tumours was observed in males. The changes, which may be associated with peroxisome proliferation, have been shown to be species-specific since they were not seen in the carcinogenicity study in mice or in other studies in mice, dogs or monkeys.

During the studies of high dose oral terbinafine in monkeys, refractile irregularities were observed in the retina at the higher doses (non-toxic effect level was 50 mg/kg). These irregularities were associated with the presence of a terbinafine metabolite in ocular tissue and disappeared after drug discontinuation. They were not associated with histological changes.

A standard battery of in vitro and in vivo genotoxicity tests revealed no evidence of a mutagenic or clastogenic potential for the drug.

No adverse effects on fertility or other reproduction parameters were observed in studies in rats or rabbits.

6. PHARMACEUTICAL PARTICULARS

6.1.LIST OF EXCIPIENTS:

Cetostearyl alcohol BP, Cetomacrogol 1000 BP, Light liquid paraffin BP, Disodium EdetateBP, Chlorocresol BP, White soft paraffin BP, Sodium hydroxide BP, Purified Water BP.

6.2.INCOMPATIBILITIES

None stated.

6.3. SHELF LIFE

36 months

6.4. SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC in a dry place. Protect from light.

6.5.NATURE AND CONTENTS OF CONTAINER

Aluminum collapsible tube of 10 g is packed in a primary carton along with the Pack Insert.

6.6.SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Not Applicable

7.MARKETING AUTHORIZATION HOLDER

AKRITI PHARMACEUTICALSPVT LTD

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8. REGISTRATION CERTIFICATE (S) NUMBER (S):

TAN 22 HM 0359

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

21st September, 2022

10. DATE OF REVISION OF THE TEXT