LEAF INSERT

TERBESARAN CREAM 1%
(TERBINAFINE HYDROCHLORIDE 10mg/gm)

LABEL CLAIM:
Each gram cream contains :
Terbinafine HCI JP…….10mg. (1% w/w)
[JP Specs.]

QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Quantity/ gm (mg)	Quantity/ Batch	Role of Ingredient
Terbinafine Hydrochloride	10.000	[1]2.500	*Active Ingredient is calculated at 100 % potency. Adjust the quantity of API as per actual assay (OAB) if potency varies.
Liquid paraffin	60.000	15.000	humectant.
Benzyl alcohol	10.000	2.500	Antimicrobial preservative
Stearic Acid	50.000	12.500	Stiffening agent
White Petroleum Jelly	60.000	15.000	Oil base
Cetyl Alcohol	45.000	11.250	Emulsifying agent
Emulsifying Wax	50.000	12.500	Emulsifying agent
Sorbitan Monostearate	45.000	11.250	Emulsifying agent
Tween 80 (Polysorbate 80)	10.000	2.500	Emulsifying agent
De-Ionized Water	658.750	[3]167.981	Solvent
Sodium Hydroxide	2.400	[2]0.600	pH Modifier

[1]Quantity at 100% potency.
[2]For pH adjustment.
[3]2% Additional quantity of water taken to compensate evaporation losses.

Excipients with known effects:

Benzyl Alcohol: Contraindicated in children under 3 years old.

PHARMACEUTICAL FORM

Cream.

CLINICAL DATA:

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

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

DOSAGE AND 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.

CONTRA-INDICATIONS:

Hypersensitivity to the active substance, Terbinafine, or to any of the excipients

WARNING & PRECAUTION 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.

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).

DRUG INTERACTIONS:

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

REPRODUCTION, PREGNANCY AND BREAST-FEEDING:

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. 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

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

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.

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.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties (with Pharmacotherapeutic class):

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), 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 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.

Pharmacokinetics:

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

PHARMACEUTICAL DATA:

Store below 30ºC.
Protect from sunlight and moisture.
Keep out of the reach of children.

PRESENTATION:

Terbinafine 1% cream for commercial use is available in Aluminium collapsible tube with polyethylene cap & measured dose applicator. Each filled tube & applicator is packed in printed carton with the product name and batch details along with the information of the manufacturer and distributor. Stability studies show no interaction between Aluminum collapsible tube and all the formulation ingredients.

MEDICINE ON PRESCRIPTION ONLY:

List 1

MARKETING AUTHORIZATION HOLDER:

SARAN PHARMA
ABIDJAN COCODY 2 PLATEAUX DERRIERE L'EN, RUE J5, LOT 269, SECTION KX PARCELLE 104, 08 BP 3121 ABIDJAN 08 RCI

MANUFACTURED BY:

Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area,
Karachi – Pakistan.

DATE OF LAST REVISION:

November 2024