1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

TABINAGEN Cream 1% w/w

Terbinafin Cream 1% w/w

2. Qualitative and Quantitative Composition

Qualitative declaration

Terbinafin Hydrochloride 1% BP

Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Topical Cream

A white colour smooth cream.

Distribution Category: POM.

4. Clinical Particulars

4.1 Indications

The treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch/jock itch) caused by Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum) and Epidermophyton floccosum.

4.2 Posology and Method of Administration

Terbinafine Cream can be applied once or twice daily.

Duration and frequency of treatment

The likely duration of each treatment is as follows:

Tineacorporis, cruris: 1 to 2 week

Tineapedis: 1 week

Cutaneous candidiasis: 2 week

Pityriasisversicolor: 2 week

Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after two weeks, the diagnosis should be verified by a physician. Dosing in special populations:

Paediatric population: Not recommended in children under 16 years.

Elderly patients: There is no evidence to suggest that elderly patients require different dosages or experience side-effects different to those of younger patients.

Method of administration: For topical & cutaneous use.

Affected area should be cleaned and dried thoroughly before application of Terbinafine Cream. Thin layer of Cream should be applied to affected skin and surrounding area & rubbed in lightly. In the case of intertriginous infections (interdigital, intergluteal, inguinal) the application may be covered with a gauze strip, especially at night

4.3 Contraindications

Hypersensitivity to terbinafine or to any of the excipients

4.4 Special Warnings and Special Precautions for Use

Terbinafine 1% cream is for external use only. Should be used with caution in patients with lesions where alcohol could be irritating. Should not be used on face. Avoid contact with eyes. May be irritating to eyes. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.

4.5 Interaction with other medicinal products and other forms of interaction

No known drug interactions with Terbinafine Cream.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Terbinafine Cream should not be used during pregnancy, unless clearly necessary.

Breast-feeding: Terbinafine is excreted in breast milk and therefore mothers should not receive terbinafine cream whilst breast-feeding.

4.7 Effects on ability to Drive and use Machines

Not Applicable

4.8 Undesirable Effects

Local symptoms such as pruritis, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema and scab may occur application site.

These minor symptoms must be distinguished from hypersensitivity reactions such as widespread pruritis, rash, bullous eruptions and hives, which are reported in sporadic cases but require discontinuation. Terbinafine may be irritating to eyes. Rarely underlying fungal infection may be aggravated.

Adverse reactions are listed below by system organ class and 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), or not known (can not to be estimated from available data).

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.

4.9 Overdose

The low systemic absorption of topical terbinafine renders overdosage extremely unlikely.

Symptoms: If accidental ingestion of a larger amount of Terbinafine Cream be inadvertantly ingested, adverse effects include headache, nausea, epigastric pain and dizziness.

Treatment: Eliminating active substance, primarily by administration of activated charcoal and giving symptomatic therapy if needed.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacological Class: Antifungal agent

Terbinafine is an allylamine that has a broad spectrum of antifungal activity. At low concentrations Terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. 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.

5.2 Pharmacokinetic Properties

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

5.3 Preclinical Safety Data

Foetal toxicity and fertility studies in animals suggest no adverse effects. 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 100mg/kg a day. In a two-year oral carcinogenicity study in mice, no neoplastic or other abnormal findings while in rats, an increased incidence of liver tumours was observed in males but not seen in the carcinogenicity study in mice, dogs or monkeys. During high-dose studies in monkeys, refractile irregularities were observed in retina at the higher doses (non-toxic effect level 50mg/kg). A standard battery of in vitro and in vivo genotoxicity tests revealed no evidence of mutagenic or clastogenic potential.

6. Pharmaceutical Particulars

6.1 List of Excipients

Benzyl Alcohol
Cetosteryl Alcohol
Cetomacrogol 1000
White Soft Paraffin
Light Liquid Paraffin
Polysorbate 80 (Tween 80)
Disodium Edetate
Isopropyl Myristate
Stearic Acid
Sodium Hydroxide
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C, Protect from Light. Do not freeze

6.5 Nature and Contents of Container

A White colour smooth Cream filled in 15 gm aluminimum collapsible tube. Such 1 tube is packed in a Printed Carton with Packing Insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-79 4107 8096
Telefax: +91-79 4107 8062
E-mail: hiren@lincolnpharma.com
Web site: www.lincolnpharma.com

APPLICANT NAME: GENERICS AND SPECIALITIES LIMITED
9, Dave Anazodo Street, Ajao Estate, Isolo

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-79 4107 8096
Telefax: +91-79 4107 8062
E-mail: hiren@lincolnpharma.com

Web site: www.lincolnpharma.com

8. Marketing Authorization Number

To be included after obtaining first registration

9. Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

10. Date of Revision of the Text

March, 2023

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable