176 mm

189 mm

Tinea pedis, interdigital –
Topical, to the skin and surrounding areas, two times a day. Treatment should be continued for at least one week and until there is significant improvement in the clinical signs and symptoms of the disease. Treatment should not be continued beyond four weeks.
Tinea pedis, plantar –
Topical, to the skin and surrounding areas, two times a day. Treatment should be continued for two weeks. Treatment may be affected by the presence of onychomycosis. Patients with a toenail infection may be less likely to respond favourably to terbinafine therapy.
[Tinea versicolor] –
Topical, to the skin and surrounding areas, one or two times a day for two weeks.
[Cutaneous candidiasis] –
Topical, to the skin and surrounding areas, one or two times a day for one or two weeks.

Usual pediatric dose
Tinea corporis or Tinea cruris or Tinea pedis
Infants and children younger than 12 years of age: Safety and efficacy have not been established.
Children 12 years of age and older: See Usual adult and adolescent dose
[Tinea versicolor] or [Cutaneous candidiasis] –
Safety and efficacy have not been established for these indications.

Route of Administration: Topical

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S):
No case of overdosage has been reported so far. The adverse effects observed in man suggest that the main symptoms of an acute oral overdosage would be gastrointestinal, e.g., nausea or vomiting. Gastric lavage and / or symptomatic supportive treatment may then be required.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
Store below 30°C.

PACKING / PACK SIZES:
Aluminium tube of 15 gm

SHELF LIFE: 3 Years

MANUFACTURER AND PRODUCT REGISTRATION HOLDER
SM PHARMACEUTICALS SDN BHD (218620-M)
Lot 88, Sungai Petani Industrial Estate
08000 Sungai Petani
Kedah Darul Aman, Malaysia.

29.05.2025

SM PHARMACEUTICALS SDN BHD

TERBIN CREAM 1%
(TERBINAFINE HYDROCHLORIDE 10 MG)

DESCRIPTION:
A white to off white, smooth homogenous cream

COMPOSITION:
Each gram contains: Terbinafine Hydrochloride 10 mg

ACTIONS AND MODE OR MECHANISMS OF ACTION:
May be fungicidal; inhibits squalene epoxidase (a key enzyme in sterol biosynthesis in fungi), which results in a deficiency in ergosterol and a corresponding increase in squalene within the fungal cell, causing fungal cell death. Also fungistatic; interferes with membrane synthesis and growth.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS):
Absorption
Limited systemic absorption may occur; less than 5% of the topically applied terbinafine cream is absorbed.
Distribution
Terbinafin rapidly diffuses through the dermis and concentrates in the lipophilic stratum corneum.
Protein binding
Approximately 99% is bound to plasma proteins.
Half Life
Elimination –
The elimination half-life of topically absorbed terbinafine is approximately 21 hours.
Onset of action
Terbinafine cream has a rapid onset of action.
Elimination
Approximately 75% of topically absorbed terbinafine is eliminated in the urine, mostly as inactive metabolites.

INDICATIONS:
Fungal infections of the skin and nails caused by dermatophytes, eg Trichophyton (e.g., T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum. Yeast infections of the skin caused by the genus Candida (e.g., Candida albicans).
Pityriasis (tinea) versicolor due to Pityrosporum orbiculare (also known as Malassezia furfur). Note: In contrast to topical Terfin, oral Terfin is not effective in Pityriasis versicolor.

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

176 mm

189 mm

SIDE EFFECTS / ADVERSE REACTIONS:
Redness, itching or stinging occasionally occur at the site of application; however, treatment rarely has to be discontinued for this reason. These harmless symptoms should be distinguished from allergic reactions which are rare but require discontinuation.

PRECAUTIONS / WARNINGS:
Cross-sensitivity and / or related problems
Patients sensitive to the oral form of terbinafine mat be sensitive to the topical form also.
Carcinogenicity / Tumorigenicity
A 2-year carcinogenicity study in mice showed a 4% incidence of splenic hemangiosarcomas and a 6% incidence od leiomyosarcoma-like tumors of the seminal vesicles in males administered terbinafine orally in doses of 156 mg per kg of body weight (mg / kg) per day. A carcinogenicity study in rats showed a 6% incidence of liver tumors, which were associated with peroxisomal proliferation, increased enzyme activity, altered triglyceride metabolism, and skin lipomas in males administered terbinafine orally in doses of 69 mg / kg per day.
Mutagenicity
In vitro and in vivo genototixicity tests, including Ames test, mutagenicity evaluation in Chinese hamsters ovarian cells, chromosome aberration test, sister chromatid exchanges, and mouse micronucleus test, revealed no evidence of mutangenic or clastogenic potential of terbinafine.
Pregnancy / Reproduction
Fertility – Reproductive studies in rats administered terbinafine orally in doses of up to 300 mg / kg per day did not show any adverse effects on fertility. In addition, terbinafine in doses of 150 mg per day administered intravaginally to pregnant rabbits did not increase the incidence of abortions or premature deliveries and did not affect fetal parameters.
Pregnancy – Adequate and well-controlled studies in humans have not been done.
Terbinafine was not teratogenic when it was administered orally at doses of up to 300 mg / kg per day during organogenesis in rats and rabbits, administered subcutaneously at doses of up to 100 mg / kg per day in rats, or administered percutaneously at doses of up to 150 mg / kg per day in rabbits.
Breast-feeding
Terbinafine is distributed into breast milk after oral administration. However, it is not known whether terbinafine is distributed into breast milk after topical administration. Breast-feeding women should avoid applying topical terbinafine to the breasts.
Terbinafine was administered orally in single 500-mg doses to two breast-feeding women. The total amounts of terbinafine recovered in the breast milk during the following 72-hour period were 0.65 mg and 0.15 mg. These amounts corresponds to 0.13% and 0.03% of the administered dose, respectively.
Pediatrics
No information is available on the relationship of age to the effects of terbinafine in pediatric patients. Safety and efficacy have not been established in infants and children up to 12 years of age.
Geriatrics
No information is available on the relationship of age to the effects of terbinafine in geriatric patients.
Pregnancy and Lactation
Foetal toxicity and fertility studies in animals suggest no adverse effects. Since clinical experience in pregnant women is not available, Terfin should not be used during pregnancy unless the potential benefits outweigh any potential risks. Terfin is excreted in breast milk; therefore mothers receiving oral treatment with Terfin should not breastfeed. When used topically, the small amounts absorbed through the skin are unlikely to affect the infant.

DRUG INTERACTIONS:
According to the results from studies undertaken in vitro and in healthy volunteers, terbinafine shows negligible potential for inhibiting or inducing the clearance of drugs that are metabolised via the cytochrome P-450 systems (e.g., ciclopsorin, tolbutamide, oral contraceptives). The plasma clearance of terbinafine may, however, be accelerated by drugs which induce metabolism (e.g., rifampicin) and may be inhibited by drugs which inhibit cytochrome P-450 (e.g., cimetidine). Where co-administration of such agents is necessary, the dosage of Terfin may need to be adjusted accordingly.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:
Usual adult and adolescent dose
Tinea corporis or Tinea cruris –
Topical, to the skin and surrounding areas, one or two times a day. Treatment should be continued for at least one week or until there is significant improvement in the clinical signs and symptoms of the disease. Treatment should not be continued beyond four weeks.