MYCODERM Tablets

(Terbinafine Tablets USP)

مائیکوڈرم گولیاں

(ٹربینافین)

COMPOSITION:
Each tablet contains:
Terbinafine USP … 125mg or 250mg (as Terbinafine HCl).
[USP Specs]

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION: Terbinafine is an allylamine which has a broad spectrum of activity against fungal pathogens of the skin, hair and nails including dermatophytes. At low concentrations Terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Its activity against yeasts is fungicidal or fungistatic, depending on the species. Terbinafine interferes specifically with fungal sterol biosynthesis at an early stage through inhibition of the enzyme squalene epoxidase. 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 P450 system.

PHARMACOKINETICS: Absorption: Following oral administration, Terbinafine is well absorbed (>70%). A single oral dose of 250mg Terbinafine resulted in mean peak plasma concentrations of 1.30μg/ml within 1.5 hours after administration. The absorption half-life is 0.8 hours and the distribution half-life is 4.6 hours. The bioavailability of Terbinafine is moderately affected by food (increase in the AUC of less than 20%), but not sufficiently to require dose adjustments.
Distribution: Terbinafine binds strongly to plasma proteins. It rapidly diffuses through the dermis and concentrates in the lipophilic stratum corneum. Terbinafine is also secreted in sebum, thus achieving high concentrations in hair follicles, hair and sebum rich skins. There is also evidence that Terbinafine is distributed into the nail plate within the first few weeks of commencing therapy.
Metabolism: Terbinafine is metabolised rapidly and extensively by at least seven CYP isoenzymes with major contributions from CYP2C9, CYP1A2, CYP3A4, CYP2C8 and CYP2C19. Biotransformation results in metabolites with no antifungal activity.
Elimination: Metabolites are excreted predominantly in the urine. The elimination half-life is 17 hours. There is no evidence of accumulation in the plasma. No clinically-relevant age-dependent changes in pharmacokinetics have been observed but the elimination rate may be reduced in patients with renal or hepatic impairment, resulting in higher blood levels of terbinafine. Single dose pharmacokinetic studies in patients with renal impairment (creatinine clearance <50ml/min) or with pre-existing liver disease have shown that clearance of Terbinafine may be reduced by about 50%.

INDICATIONS: Mycoderm is indicated in fungal infections of the skin and nails caused by Trichophyton (eg. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum. Tinea capitis. Mycoderm tablet is indicated in the treatment of ringworm (tinea corporis, tinea cruris and tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection and also in the treatment of onychomycosis.

CONTRA-INDICATIONS: Hypersensitivity to the active substance or to any of the excipients of the product. Oral Terbinafine is contra-indicated in severe renal impairment and severe hepatic impairment.

DOSAGE AND ADMINISTRATION: Mycoderm Tablets: The duration of treatment varies according to the indication and severity of the infection.
Adult: 250mg once daily.
Skin Infections: Recommended duration of treatment;
Tinea pedis (interdigital, planter/moccasin type) 2 to 6 weeks.
Tinea corporis: 2 to 4 weeks.
Tinea cruris: 2 to 4 weeks.
Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure.
Hair and Scalp Infection: Recommended duration of treatment:
Tinea capitis: 4 weeks.
Tinea capitis occurs primarily in children.
Onychomycosis: In most patients the duration of successful treatment is 6-12 weeks. Fingernail onychomycosis: In most cases 6 weeks' treatment is sufficient in fingernail onychomycosis. Toenail onychomycosis: In most cases 12 weeks' treatment is sufficient in toenail onychomycosis although a few patients may require treatment up to 6 months. Poor nail outgrowth during the first weeks of treatment may enable identification of those patients in whom longer therapy is required. Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure and is only seen several months after stopping treatment, which is the time for growth of a healthy nail.

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Pediatric Patients:
No data is available in children under two years of age (usually <12kg).
Children weighing <20kg 62.5mg once daily.
Children weighing 20 to 40kg 125mg once daily.
Children weighing >40kg 250mg once daily.
Method of administration: Tablets are taken orally with water. They should preferably be taken at the same time each day and can be taken on an empty stomach or after meal.

OVERDOSAGE: A few cases of over dosage (up to 5g) by oral route have been reported. These include headache, nausea, epigastric pain and dizziness. The recommended treatment of over dosage insists in elimination of the drug, primarily by the administration of activated charcoal, and going symptomatic supportive therapy, if needed.

WARNING AND PRECAUTIONS: Liver Functions: Terbinafine Tablet is not recommended for patients with chronic or active liver disease. Terbinafine should be immediately discontinued in case of elevation of liver function tests. Patients prescribed, Terbinafine Tablet should be warned to report immediately to their physician any symptoms of suggestive of liver dysfunction such as pruritus, unexplained persistent nausea, decreased appetite, anorexia, jaundice, vomiting, fatigue, right upper abdominal pain, dark urine, or pale stools. Patients with these symptoms should discontinue taking oral Terbinafine and the patient's liver function should be immediately evaluated.
Special Population: Pregnancy: It is recommended that treatment with Terbinafine should not be initiated during pregnancy.
Nursing Mothers: Treatment with Terbinafine Tablets is not recommended in women who are nursing.
Pediatric Use: The safety and efficacy of Terbinafine Tablets have not been established in pediatric patients with onychomycosis.
Renal Impairment: The use of Terbinafine Tablets has not been adequately studied in patients with renal impairment and is therefore not recommended.
Geriatric Patients: There is no evidence to suggest that elderly patients (aged 65 years and above) require different dosages or experience different side effects than younger patients. When prescribing Terbinafine Tablets for patients in this age group, the possibility of pre-existing impairment of liver.

UNDESIRABLE EFFECTS: Side effects are generally mild to moderate, and transient. The following adverse reactions have been observed with the use of oral Terbinafine: Decreased appetite, headache, anaphylactoid reactions (including angioedema), cutaneous and systemic lupus erythematosus, gastrointestinal symptoms (feeling of fullness abdominal distension, dyspepsia, nausea, abdominal pain, diarrhea), taste disturbances, including taste loss, rash, urticaria, abnormal liver function tests & gas.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:
Effect of other medicinal products on oral Terbinafine: The plasma clearance of Terbinafine may be accelerated by drugs which induce metabolism and may be inhibited by drugs which inhibit cytochrome P450. Where co-administration of such agents is necessary, the dosage of Terbinafine may need to be adjusted accordingly. The following medicinal products may increase the effect or plasma concentration of Terbinafine: Cimetidine decreases the clearance of Terbinafine by 30%. Fluconazole increases the Cmax and AUC of Terbinafine by 52% and 69% respectively, due to inhibition of both CYP2C9 and CYP3A4 enzymes. Similar increase in exposure may occur when other drugs which inhibit both CYP2C9 and CYP3A4 such as ketoconazole and amiodarone are concomitantly administered with Terbinafine.
Rifampicin many decrease the effect or plasma concentration of Terbinafine. It increases the clearance of Terbinafine by 100%
Effect of oral Terbinafine on other medicinal products: Terbinafine may decrease the clearance of caffeine administered intravenously by 21%. Terbinafine may decrease the clearance of desipramine by 82%. Terbinafine may increase the clearance of ciclosporin by 15%.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
Mycoderm (Terbinafine) 125mg & 250mg Tablets are available in blister pack size of 10's tablets.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
PHARMA 17/24, Korangi Industrial Area, Karachi-Pakistan.
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