Ternafin Tablet 250mg

DESCRIPTION

White to off-white round tablet with a score on one side.

COMPOSITION

Each tablet contains: Terbinafine Hydrochloride equivalent to Terbinafine 250mg

ACTION AND PHARMACOLOGY

Ternafin tablet is an antifungal agent. It is an allylamine derivative with a broad spectrum of antifungal activity. Terbinafine is fungicidal against dermatophytes, moulds and certain fungi. The activity against yeasts is fungicidal or fungistatic, depending on the species.

Pharmacodynamics

Terbinafine is an allylamine which has a broad spectrum of activity against fungal pathogens of the skin, hair and nails including dermatophytes, e.g. Trichophyton (e.g., T. rubrum, T.mentagrophytes, T. verrucosum, T. tonsurans, T. violaceum), Microsporum (e.g., M. canis), Epidermophyton floccosum, and yeasts of the genera Candida (e.g. C. albicans) and Pityrosporum. At low concentrations, terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Terbinafine is either fungicidal or fungistatic against yeasts, depending on the species.
It acts through inhibition of fungal sterol synthesis. When given orally, the drug concentrates in skin, hair and nails at levels associated with fungal activity.

Pharmacokinetics

Absorption and Distribution:

Terbinafine hydrochloride is well absorbed from the gastrointestinal tract. About 40% of a dose undergoes first-pass hepatic metabolism. A single oral dose of 250 mg terbinafine results in peak plasma concentrations of 0.97 jig/ml within 2 hrs of administration. Steady state concentrations are about 25% higher than those seen after a single dose and are reached in 10 to 14 days. 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, but dose adjustment is not required. Terbinafine binds strongly to plasma proteins (99%). 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, nail plate, hair and sebum-rich skin where it reaches concentrations considerably higher than those found in plasma. Distribution into the nail plate occurs in the first few weeks after commencing therapy.

Metabolism and Excretion:

Terbinafine is metabolized rapidly and extensively by at least 7 CYP isoenzymes with major contributions from CYP2C9, CYP1A2, CYP3A4, and CYP2C8 and CYP2C19. Biotransformation occurs in the liver and results in inactive metabolites with no antifungal activity, which are excreted predominantly in the urine. A plasma elimination half-life varying from 11 to 17 hours and a terminal elimination half-life of up to 400 hours in patients receiving prolonged therapy, probably representing elimination from skin and adipose tissue. Fungicidal concentrations in nails are maintained for several weeks after therapy is discontinued. There is no evidence of accumulation. No age-dependent changes in steady-state plasma concentrations have been observed, but the elimination rate may be reduced in patients with renal or hepatic impairment, resulting in higher blood levels of terbinafine.

INDICATIONS

Fungal infections of the skin and nails caused by Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum.
Onychomycosis (fungal infection of the nail) caused by dermatophyte fungi.
Fungal infections of the skin for the treatment of ringworm (tinea corporis, tinea cruris, tinea pedis) and yeast infections of the skin caused by the genus Candida (e.g., Candida albicans) where oral therapy is generally considered appropriate owing to the site, severity or extent of the infection. It is not effective in pityriasis versicolor.

CONTRAINDICATIONS

Hypersensitivity to terbinafine or to any excipients of Ternafin Tablets.

SIDE EFFECTS

In general, Ternafin Tablet is well tolerated. Side effects are usually mild to moderate and transient. The most common gastrointestinal symptoms (feeling of fullness, loss of appetite or anorexia, dyspepsia, nausea, mild abdominal pain, diarrhoea), headache, nonserious forms of skin reactions (rash, urticaria), musculoskeletal reactions (arthralgia, myalgia).
Uncommon (≥ 0.1%): Taste disturbances, including taste loss, which usually recover within several weeks after discontinuation of the drug.
Rare (≥ 0.01% to <0.1%): Hepatobiliary dysfunction (primarily cholestatic in nature, hepatitis, jaundice) has been reported in association with Ternafin treatment, including very rare cases of liver failure (see Precautions).
Very rare (<0.01%): Serious skin reactions (e.g., cutaneous lupus erythematosus, pustulosis, Stevens Johnson syndrome, toxic epidermal necrolysis, photosensitivity and angioneurotic oedema) and anaphylactoid reactions have been reported. If progressive skin rash occurs, Ternafin treatment should be discontinued. Haematological disorders, eg neutropenia, agranulocytosis or thrombocytopenia have been reported. Hair loss has been reported, although a causal relationship has not been established.

PRECAUTIONS

The therapeutic use of TERNAFIN in patients with chronic or active liver disease has not been studied and therefore cannot be recommended. (see Side Effects).
If a patient presents with signs or symptoms suggestive of liver dysfunction, e.g. unexplained persistent nausea, anorexia or tiredness, or jaundice, dark urine or pale stools, hepatic origin should be verified and Ternafin therapy should be discontinued (see Side Effects).
Patients with impaired renal function (creatinine clearance <50mL/min or serum creatinine >300 µmol/L) should receive half the normal dose.
In vitro studies have shown that terbinafine inhibits the CYP2D6 metabolism. Therefore, patients receiving concomitant treatment with drug predominantly metabolised by this enzyme, e.g. tricyclic antidepressants (TCAs), β-blockers, selective serotonin re-uptake inhibitors (SSRIs) and monoamine oxidase inhibitors (MAOIs) type B, should be followed, if the co-administered drug has a narrow therapeutic window (see Interactions). It has been suggested that terbinafine may provoke or exacerbate psoriasis. Therefore, it should not be given to these patients.
Effects on Ability to Drive or Operate Machinery: There are no data on whether Ternafin Tablet

affects the ability to drive and use machinery.
Pregnancy and Lactation: Foetal toxicity and fertility studies in animals suggest no adverse effects. Since clinical experience in pregnant women is very limited, Ternafin Tablet should not be used during pregnancy unless the potential benefits outweigh any potential risks. Ternafine is excreted in breast milk; mother receiving oral treatment with Ternafin Tablet should therefore not breastfeed.

DRUG INTERACTION

Studies undertaken in vitro and in healthy volunteers showed that terbinafine has negligible potential for inhibiting or enhancing the clearance of most drugs that are metabolised via the cytochrome P-450 system (e.g., cyclosporin, terfenadine, triazolam, tolbutamide or oral contraceptives).
However, in vitro studies have shown that terbinafine inhibits the CYP2D6-mediated metabolism. This finding may be of clinical relevance for compounds predominantly metabolised by this enzyme, e.g. tricyclic antidepressants (TCAs), b-blockers, selective serotonin re-uptake inhibitors (SSRIs) and monoamide oxidase inhibitors (MAOIs) type B, and if they also have a narrow therapeutic window. (See Precautions).
Some cases of menstrual irregularities have been reported in patients taking Ternafin Tablet concomitantly with oral contraceptives, although the incidence of these disorders remains within the background incidence of patients taking oral contraceptives alone. On the other hand, the plasma clearance of terbinafine may be accelerated by drugs which induce metabolism (eg, rifampicin) and may be inhibited by drugs which inhibit cytochrome P-450 (e.g., cimetidine). Where coadministration of such agents is necessary, the dosage of Ternafin Tablet may need to be adjusted accordingly.
Besides, raised serum concentrations of nortriptyline and associated symptoms of intoxication occurred in a patient during concomitant treatment with terbinafine, the interaction was confirmed on rechallenge.

DOSAGE AND ADMINISTRATION

The duration of treatment varies according to the indication and the severity of the infection.
Adults: 250 mg once a day.
Children: 20 – 40 kg: 125 mg once daily; > 40 kg: 250 mg once daily. In children > 2 year, Ternafin Tablet was well tolerated.
No data are available in children < 2 years (usually < 12 kg).
Elderly: There is no evidence to suggest that elderly patients require different dosages or experience different side effects than younger patients. When prescribing tablets for patients in this age group, the possibility of preexisting impairment of liver or kidney function should be considered (see Precautions).
Skin Infections: Recommended Duration of Treatment: Tinea pedis (interdigital, plantar/moccasin type): 2-6 weeks; tinea corporis, cruris: 2-4 weeks; cutaneous candidiasis: 2-4 weeks. Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure.
Onychomycosis: For most patients, the duration for successful treatment is between 6 –12 weeks.
Six weeks of therapy is sufficient for fingernail onychomycosis in most cases.
Twelve weeks of therapy is sufficient for toenail onychomycosis in most cases. Some patients with

poor nail outgrowth may require longer treatment. The optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail.
Method of Administration: Via the oral route

OVERDOSAGE AND TREATMENT
Overdosage (up to 5 g) giving rise to headache, nausea, epigastric pain and dizziness. The recommended treatment of overdosage includes eliminating the drug by the administration of activated charcoal, and giving symptomatic supportive therapy.

PRESENTATION
A blister of 10 tablets. Box of 1, 4 and 10 stripes.
A blister of 14 tablets. Box of 1, 3 or 7 stripes.

STORAGE
Store in a cool dry place below
30°C. Protect form light.
Keep out of reach of children.

Manufactured by:
Noripharma Sdn. Bhd. 200701034604 (792633-A)
Lot 5030, Jalan Teratai,
5 1/2 Mile off Jalan Meru,
41050 Klang, Selangor,
Malaysia.

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