TERBINOX

TERBINAFINE HYDROCHLORIDE BP

Compositions:
Terbinox Tablet: Each film-coated tablet contains Terbinafine 250 mg as Terbinafine Hydrochloride BP. Terbinox Cream: Each gram of cream contains Terbinafine Hydrochloride BP 10 mg

Pharmacology:
Terbinafine, an Allylamine antifungal, inhibits biosynthesis of Ergosterol (an essential component of the fungal cell membrane) via inhibition of Squalene Epoxidase enzyme. This results in fungal cell death primarily due to the increased membrane permeability mediated by the accumulation of high concentrations of Squalene but not due to Ergosterol deficiency. Depending on the concentration of the drug and the fungal species test in vitro, Terbinafine hydrochloride may be fungicidal. However, the clinical significance of in vitro data is unknown. Terbinafine has been shown to be active against most strains of the following microorganisms both in vitro and in clinical infections: Trichophyton Mentagrophyte, Trichophyton Rubrum, Candida albicans, Epidermophyton floccosum, Scopulariopsis brevicaulis, Malassezia furfur.

Dosage And Administration:
Terbinox Tablet: 1. For the treatment of fingernail onychomycosis: Terbinafine 250 mg (one tablet), once daily for 6 weeks. 2. For the treatment of toenail onychomycosis: Terbinafine 250 mg (one tablet), once daily for 12 weeks. 3. The optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for the outgrowth of a healthy nail. Terbinox Cream: Terbinox cream can be applied once or twice daily. Cleanse and dry the affected areas thoroughly before application of the Terbinox cream. Apply the cream to the affected skin and the surrounding area in a thin layer and rub it lightly. In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal) the application may be covered with a gauze strip, especially at night. The likely duration of treatment is as follows: 1. Tinea corporis, cruris: 1 to 2 weeks, 2. Tinea pedis: 1 week, 3. Cutaneous candidiasis: 2 weeks, 4. Pityriasis Versicolor: 2 weeks. Relief of the 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.

Contraindications:
Terbinafine tablets and creams are contraindicated in individuals hypersensitive to terbinafine.

Warning And Precaution:
Terbinox Tablet: Rare cases of liver failure, some leading to death or liver transplant, have occurred with the use of terbinafine tablets for the treatment of onychomycosis in individuals with and without preexisting liver disease. Treatment with terbinafine tablets should be discontinued if there is biochemical or clinical evidence of liver injury. There have been isolated reports of serious skin reactions (e.g., Stevens - Johnson syndrome and toxic epidermal necrolysis). If progressive skin rash occurs, treatment with terbinafine should be discontinued. Terbinox Cream: Terbinafine cream is for external use only. Contact with the eyes should be avoided.

Side Effects:
The adverse events reported encompassing gastrointestinal symptoms (including diarrhea, dyspepsia, and abdominal pain), liver test abnormalities, rashes, urticaria, pruritus, and taste

disturbances. Adverse events, based on worldwide experience with terbinafine use, include idiosyncratic and symptomatic hepatic injury and more rarely, cases of liver failure, some leading to death or liver transplant, serious skin reactions, severe neutropenia, thrombocytopenia, angioedema, and allergic reactions (including anaphylaxis). Other adverse reactions that have been reported include malaise, fatigue, vomiting, arthralgia, myalgia, and hair loss.

Use in Pregnancy and Lactation:
Terbinox Tablet: There are no adequate and well-controlled studies in pregnant women. It is recommended that terbinafine not be initiated during pregnancy. After oral administration, terbinafine is present in the breast milk of nursing mothers. Treatment with terbinafine is not recommended in nursing mothers. Terbinox Cream: Foetal toxicity and fertility studies in animals suggest no adverse effects. There is no clinical experience with terbinafine in pregnant women; therefore, unless the potential benefits outweigh any potential risk, terbinafine should not be administered. Terbinafine is excreted in breast milk and therefore mothers should not receive terbinafine treatment whilst breastfeeding.

Drug Interaction:
Co-administration of terbinafine should be done with careful monitoring and may require a reduction in dose of the CYP450 2D6-metabolized drug e.g. TCA, SSRI, ¿-blockers, MAO inhibitors.

Overdosage:
Clinical experience regarding overdose with terbinafine tablets is limited. Doses up to 5 gm (20 times the therapeutic daily dose) have been taken without inducing serious adverse reactions. The symptoms of overdose included nausea, vomiting, abdominal pain, dizziness, rash, frequent urination, and headache.

Storage:
Store in cool and dry place (below 30°C), protect from light. Keep out of reach of children.

Packing:
Terbinox Tablet: Each box contains 1 X 10 tablets in Alu-Alu blister strip. Terbinox Cream: Each tube contains 10 gm cream.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.