

Terbex®

Cream/Tablet

Description

Terbex is a preparation of Terbinafine Hydrochloride. Terbinafine is an allylamine with a range of antifungal activity. It is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Terbinafine is either fungicidal or fungistatic against yeasts, depending on the species. Terbinafine interferes with fungal ergosterol biosynthesis by inhibiting squalene epoxidase in the fungal cell membrane at an early stage. This leads to a deficiency in ergosterol and to intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine is highly effective in fungal infections of the skin, hair and nails caused by *Trichophyton spp.*, *Microsporum spp.* and *Epidermophyton floccosum*. It is also effective against yeast infections of the skin, principally those caused by the genus *Candida*. Topical terbinafine appears to be effective in pityriasis versicolor due to *Pityrosporum orbiculare*.

Indications

Terbex cream is indicated for the treatment of the following dermatological infections : interdigital tinea pedis (Athlete's foot), tinea cruris (jock itch) or tinea corporis (ring worm) due to susceptible organisms and planter tinea pedis (moccasin type) due to *Trichophyton spp.*

Terbex tablet is indicated for the treatment of onychomycosis of the toe nail or finger nail due to dermatophytes and also by non-dermatophyte fungi.

Dosage and Administration

Topical application of Terbex cream to affected areas once or twice daily for 1-2 weeks may be adequate for fungal infections of the skin but certain infections may require oral Terbex tablet therapy.

Usual duration of treatment of Terbex cream in Tinea corporis and Tinea cruris : 1-2 weeks. In Tinea pedis : 2 - 4 weeks (One week of treatment will normally suffice if the cream is applied twice daily.). In Cutaneous candidiasis : 1-2 weeks and in Pityriasis (tinea) versicolor : 2 weeks.

To prevent relapses in fungal infection, treatment should be continued for a adequate length of time. To apply Terbex cream clean and dry the affected areas thoroughly and apply the cream once or twice a day to the affected skin and surrounding area in a thin layer and rub in lightly. In the case of intertriginous infections the application may be covered with a gauze strip, especially at night.

Oral administration of Terbex tablet is essential for hair or nail infections. The usual oral dose is 1 Terbex tablet (250 mg) daily for 2 to 12 weeks depending upon the infection. Finger nail onychomycosis : 1 Terbex tablet (250 mg) once daily for 6 weeks. Toe nail onychomycosis : 1 Terbex tablet (250 mg) once daily for 12 weeks.

Contraindication

Hypersensitivity to Terbinafine or any of the excipients in the preparation.

Side Effects

In general, the side effects are mild, transient and do not lead to discontinuation of therapy. The side effects reported include gastrointestinal disturbances (diarrhoea, dyspepsia, and abdominal pain), rashes etc. Rarely, cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported. Besides, there have been isolated reports of serious skin reactions. If progressive skin rash occurs, treatment should be discontinued.

Use in Special Population

Children : Experience with topical Terbex in children is limited and its use cannot therefore be recommended.

Commercial Packs

Terbex[®] Cream : Tubes containing 5 g cream, each gram contains Terbinafine Hydrochloride INN 10 mg.

Terbex[®] Tablet : Box containing 1 blister strip of 10 tablets, each tablet contains Terbinafine Hydrochloride INN equivalent to 250 mg Terbinafine.