

# Trec<sup>®</sup>

Itraconazole

## COMPOSITION:

Trec<sup>®</sup> 100 Capsule: Each Capsule contains Itraconazole Pellets 430 mg equivalent to Itraconazole USP 100 mg.

Trec<sup>®</sup> 200 Tablet: Each film coated tablet contains Itraconazole USP 200 mg.

## PHARMACOLOGY:

Itraconazole is an orally active triazole antifungal drug that has demonstrated a broad spectrum of activity and favorable pharmacokinetic profile. Itraconazole inhibits Cytochrome P-450 dependent enzymes resulting in impairment of the biosynthesis of ergosterol, a major component of the cell membrane of yeast and fungal cells. Being integral to the proper functioning of the cell membrane, inhibition of the synthesis of ergosterol leads to a cascade of abnormalities in permeability, membrane bound enzyme activity, and co-ordination of chitin synthesis leading to inhibition of growth, abnormal cell wall formation and accumulation of intracellular lipids and membranous vesicles.

## INDICATION:

Trec<sup>®</sup> is used for the treatment of oropharyngeal candidiasis, vulvovaginal candidiasis, pityriasis versicolor, tinea pedis, tinea cruris, tinea corporis, tinea manuum, onychomycosis, histoplasmosis. It is indicated in the treatment of systemic candidiasis, aspergillosis, and cryptococcosis (including cryptococcal meningitis). It is also used for maintenance therapy in AIDS patients to prevent relapse of underlying fungal infections and in the prevention of fungal infection during prolonged neutropenia infections (including meningitis).

## DOSE & ADMINISTRATION:

Oropharyngeal candidiasis: 100 mg daily (200 mg daily in AIDS or neutropenia) for 15 days.

Vulvovaginal candidiasis: 200 mg twice daily for 1 day.

Pityriasis versicolor: 200 mg daily for 7 days.

Tinea corporis and tinea cruris: either 100 mg daily for 15 days or 200 mg daily for 7 days.

Tinea pedis and tinea manuum: either 100 mg daily for 30 days or 200 mg twice daily for 7 days.

Onychomycosis: either 200 mg daily for 3 months or course (pulse) of 200 mg twice daily for 7 days, subsequent courses repeated after 21 days interval.

Fingernails two courses, toenails three courses.

Systemic infections (aspergillosis, candidiasis and cryptococcosis including cryptococcal meningitis) where other antifungal drugs inappropriate or ineffective: 200 mg once daily, increased in invasive or disseminated disease and in cryptococcal meningitis to 200 mg twice daily.

Histoplasmosis: 200 mg 1-2 times daily. Maintenance in AIDS patients to prevent relapse of underlying-fungal infection & prophylaxis in neutropenia when standard therapy is inappropriate: 200 mg once daily, increased to 200 mg twice daily if low plasma Itraconazole concentration is detected.

Child dose: the recommended dose is 3 to 5 mg/kg/day.

## CONTRA-INDICATION:

Itraconazole is contraindicated in patients with known hypersensitivity to the drug or any ingredient in the formulation. Patients who have severe hepatic disease are not advised to take Itraconazole. It is not advisable to use the drug in patients taking rifampin, which appears to initially inhibit and then enhance the metabolism of Itraconazole.

## WARNING & PRECAUTION:

Absorption is impaired when gastric acidity is reduced. In patients receiving acid neutralizing medicines (e.g. aluminium hydroxide), these should be administered at least 2 hours after the intake of Itraconazole. The drug should be administered after a full meal. Rarely, cases of hepatitis and jaundice have been reported mainly in patients treated for longer than one month. It is therefore, advised to monitor liver function in patients receiving continuous treatment of more than one month.

## SIDE EFFECT:

Nausea, abdominal pain, dyspepsia, constipation, headache, dizziness, raised liver enzymes, menstrual disorders, allergic reactions (including pruritus, rash, urticaria and angioedema), hepatitis and cholestatic jaundice, peripheral neuropathy and Stevens-Johnson syndrome reported. On prolonged use hypokalaemia, oedema and hair loss reported.

## USE IN PREGNANCY & LACTATION:

Itraconazole is contraindicated in pregnancy. Breast feeding while receiving Itraconazole is not recommended.

## USE IN CHILDREN AND ADOLESCENTS:

The efficacy and safety of the Itraconazole capsule have not been established in pediatric patients.

## DRUG INTERACTION:

The drugs like terfenadine, astemizole, cisapride, HMG-CoA reductase inhibitors such as simvastatin, oral midazolam or triazolam should not be given concurrently with Itraconazole. Significant interactions also observed during co-administration of rifampicin, phenytoin, phenobarbital, digoxin, and calcium channel blockers

## OVERDOSE:

There is no data found about overdosage of itraconazole.

## STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. keep out of reach of children.

## PACKING:

Trec<sup>®</sup> 100 Capsule: Each box contains of 5x4's capsules in Alu-Alu blister strips.

Trec<sup>®</sup> 200 Tablet: Each box contains of 2x7's tablets in Alu-Alu blister strips.



Manufactured by

**Team Pharmaceuticals Ltd.**

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