

ITRAVIZ

Capsules
100 mg

Itraconazole (USP)

اٹراویز
۱۰۰ ملی گرام
کپسولز
(اٹراکونازول)

COMPOSITION:

Each Capsule Contains: Itraconazole (as coated pellets) ... 100mg

MODE OF ACTION:

Itraviz (Itraconazole) is a tri-azole antifungal agent that inhibits the synthesis of ergosterol, a vital component of fungal cell membranes.

PHARMACOKINETICS:

The oral bioavailability of itraconazole is maximal when taken with a full meal. Steady state of plasma concentration is achieved within 15 days during daily dosing. Itraconazole is highly protein bounded only 0.2% circulates as free drug. Itraconazole is metabolized in liver to various metabolites mainly by cytochrome p450 isoenzyme CYP 3A4. The major bioactive metabolite is hydroxyitraconazole. Concentrations of itraconazole in fatty tissues, omentum, liver, kidney and skin tissues range from 2-20 times greater than its plasma concentrations. The Elimination half life following a single oral dose has been reported as 20 hours which increases to 30-40 hours with continued administration.

CLINICAL MICROBIOLOGY:

Itraconazole is a broad-spectrum antifungal agent, having a wider spectrum activity than ketoconazole and is active against a wide variety of organisms, including Blastomyces dermatitidis, Histoplasma capsulatum, Histoplasma duboisii, Aspergillus flavus, Aspergillus fumigatus and Cryptococcus neoformans. It has in vitro activity also against Trichophyton spp., Candida albicans and other Candida spp.

INDICATIONS:

Itraviz (Itraconazole) is indicated for the treatment of the following fungal infections: onychomycosis, tinea cruris, tinea corporis, tinea pedis/manus, pityriasis versicolor, oral candidiasis, vulvovaginal candidiasis, fungal keratitis, aspergillosis, candidosis, histoplasmosis and sporotrichosis. Dose adjustment is required for hepatic and renal function impairment patients.

DOSAGE AND ADMINISTRATION

Indication	Dose(mg)	Duration
Tinea cruris	200 o.d.	7 days
Tinea corporis	200 o.d.	7 days
Tinea pedis/manus*	200 o.d.	7 days
Pityriasis versicolor	200 o.d.	7 days
Oral candidiasis	100 o.d	15 days
Vulvovaginal candidiasis	200 mg b.i.d.	1 day
Fungal keratitis	200 o.d.	21 days
Aspergillosis	200 o.d.	1-2 years
Candidosis	100-200 o.d.	3 weeks-7 months
Histoplasmosis	200 o.d.	8 months
Sporotrichosis	200 o.d.	6 months
Blastomycosis	200 b.i.d	6 months

*The dose for planter T. pedis and palmer T. manus is 200 mg b.i.d

PULSE THERAPY FOR ONYCHOMYCOSIS

Toenails	
Week 1	200 mg b.i.d
Week 2	Drug Holiday
Week 3	Drug Holiday
Week 4	Drug Holiday
Week 5	200 mg b.i.d
Week 6	Drug Holiday
Week 7	Drug Holiday
Week 8	Drug Holiday
Week 9	200 mg b.i.d
Fingernails	
Week 1	200 mg b.i.d
Week 2	Drug Holiday
Week 3	Drug Holiday
Week 4	Drug Holiday
Week 5	200 mg b.i.d.

CONTRAINDICATIONS:

Itraviz should not be administered for the treatment of onychomycosis to pregnant patients or to women contemplating pregnancy. Itraviz is contraindicated in patients who have shown hypersensitivity to the drug or any of the excipients.

DRUG INTERACTIONS:

Concomitant administration of itraconazole and drugs metabolized by cytochrome P450 3A4 isoenzyme system (CYP 3A4) may result in increased concentration of the following drugs: terfenadine, astemizole, cisapride, triazolam, oral midazolam, quinidine, dofetilide, pimozide, and HMG CoA-reductase inhibitors (such as simvastatin). The concomitant administration of itraconazole with the above drugs is contraindicated. Itraconazole may interfere with the metabolism, or get its metabolism affected by, co-administration with the following drugs: digoxin, carbamazepine, phenytoin, Phenobarbital, macrolide antibiotics (such as erythromycin and clarithromycin) vinca alkaloids, alprazolam, diazepam, verapamil, atorvastatin, immunosuppressants, oral hypoglycemics, antacids, H₂ receptor antagonists, proton pump inhibitors and protease inhibitors.

ADVERSE EFFECTS:

Itraviz (Itraconazole) is generally well tolerated. The side effects seen most frequently during clinical trials are: elevated liver enzymes, nausea, vomiting, diarrhea, anorexia, rash, orthostatic hypotension, headache, malaise, myalgia, vasculitis, vertigo, edema, etc.

PRECAUTIONS:

- Itraconazole should not be administered to treat onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure or a history of congestive heart failure. Patients with preexisting hepatic abnormality should be routinely monitored by laboratory tests. All other patients who undergo itraconazole therapy continuously for more than one month, or those who develop any hepatic pathology symptoms, should be regularly checked for liver dysfunction.
- Itraviz should be administered after a full meal. The absorption of itraconazole may be decreased with the concomitant administration of antacids or gastric acid secretion suppressors.
- Itraconazole does not have carcinogenic or mutagenic potential at therapeutic dosage ranges.
- Itraconazole was found to cause a dose-related increase in maternal toxicity, embryotoxicity and teratogenicity in rats. It is suggested therefore that itraconazole should be used for treatment of systemic fungal infections in pregnancy only if the contemplated benefit outweighs the potential risk. Itraconazole is contraindicated for the treatment of onychomycosis in pregnant patients or to those women who are planning a pregnancy. Itraviz is also contraindicated in women of child-bearing age for the treatment of onychomycosis unless they are taking effective measure to prevent pregnancy and the patient begins therapy on the second or third day of the next normal menstrual period. It is recommended that effective contraception should be continued throughout Itraviz therapy and for two months after cessation of treatment.
- Since itraconazole is excreted in breast milk, it should not be administered to nursing women.
- The efficacy and safety of Itraviz have not been established in pediatric patients. The long term effect of itraconazole in pediatric patients is unknown.

HOW SUPPLIED:

Itraviz (Itraconazole Capsules) is available in a pack of 1 x 4's.

STORAGE:

Store at room temperature (15°-30°C). Protect from light, heat and moisture.



Manufactured by:

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