Itraconazole Capsules

ITROTAB®

Composition:
Each hard gelatin capsule contains:
Itraconazole BP 100mg
(In the form of pellets)
Excipients q.s.
Approved colour used in empty capsule shell.

Each hard gelatin capsule contains:
Itraconazole BP 200mg
(In the form of pellets)
Excipients q.s.
Approved colour used in empty capsule shell.

Indications:
Vulvovaginal candidiasis; pityriasis versicolor; tinea corporis; tinea cruris; tinea pedis; tinea manuum; onychomycosis; aspergillosis; histoplasmosis; systemic candidiasis and cryptococcosis including cryptococcal meningitis where other antifungal drugs inappropriate or ineffective; maintenance in HIV-infected patients to prevent relapse of underlying fungal infection; prophylaxis in neutropenia when standard therapy inappropriate.

Cautions:
Absorption reduced in HIV-infection and neutropenia (monitor plasma-Itraconazole concentration and increase dose if necessary); susceptibility to congestive heart failure. Ensure effective contraception during treatment and until the next menstrual period following end of treatment.

Interactions:
Aliskiren, Alfentanil, Fentanyl, Methadone, Oxycodone, antacids Disopyramide, Dronedarone, Clarithromycin, Rifabutin, Rifampicin, Apixaban, coumarins, Dabigatran, Rivaroxaban, Reboxetine, Repaglinide, Carbamazepine, Phenobarbital, Phenytoin, Amphotericin, Micafungin, Mizolastine, Piperaquine, Artenimol, Artemether with Lumefantrine, Darifenacin, Tolterodine, Fesoterodine, Solifenacin, Haloperidol, Aripiprazole, Pimozide, Quetiapine, Rrisperidone, Efavirenz, Fosamprenavir, Indinavir, Nevirapine, Ritonavir, Saquinavir, Telaprevir, Alprazolam, Midazolam, Buspirone, Bosentan, calcium-channel blockers, Felodipine, Lercanidipine, dihydropyridines, Digoxin, Ciclosporin, Cilostazol, Clopidogrel, Cobicistat, Colchicine, corticosteroids, Methylprednisolone, Budesonide, Fluticasone, Busulfan, Cyclophosphamide, Axitinib, Bosutinib, Crizotinib, Everolimus, Gefitinib, Lapatinib, Pazopanib, Ruxolitinib, Temsirolimus, Cabazitaxel, Irinotecan, Vinblastine, Vindesine, Vinflunine, Vinorelbine, Vincristine, Dapoxetine, Eplerenone, Ergometrine, Ergotamine, Eletriptan, Ivabradine, Ivacaftor, Lenalidomide, Atorvastatin, Simvastatin, Mirabegron, Ranolazine, Sildenafil, Sirolimus, Tacrolimus, Tadalafil, Histamine H2-antagonists, proton pump inhibitors, Ulipristal, Vardenafil.

Contraindications:
Acute porphyria

Hepatic impairment:
Use only if potential benefit outweighs risk of hepatotoxicity; dose reduction may be necessary. Potentially life-threatening hepatotoxicity reported very rarely, discontinue if signs of hepatitis develop. Avoid or use with caution if history of hepatotoxicity with other drugs or in active liver disease. Monitor liver function if treatment continues for longer than one month, if receiving other hepatotoxic drugs, if history of hepatotoxicity with other drugs, or in hepatic impairment. Patients should be told how to recognise signs of liver disorder and advised to seek prompt medical attention if symptoms such as anorexia, nausea, vomiting, fatigue, abdominal pain or dark urine develop.

Renal impairment:
Risk of congestive heart failure; bioavailability of oral formulations possibly reduced.

Pregnancy:
Manufacturer advises to use only in life-threatening situations (toxicity at high doses in animal studies).

Breast-feeding:
Small amounts present in milk which may accumulate; manufacturer advises to avoid.

Side-effects:
Nausea, vomiting, taste disturbances, abdominal pain, diarrhoea, hepatitis, dyspnoea, headache, hypokalaemia, rash; less commonly dyspepsia, flatulence, constipation, oedema, dizziness, peripheral neuropathy (discontinue treatment), menstrual disorder, myalgia; rarely pancreatitis, heart failure, hypertriglyceridaemia, erectile dysfunction, urinary frequency, leucopenia, visual disturbances, tinnitus, deafness, alopecia, photosensitivity, toxic epidermal necrolysis, Stevens-Johnson syndrome; also reported, blood pressure changes, confusion, drowsiness, tremor, thrombocytopenia, renal impairment, arthralgia.

Dosage:

- Vulvovaginal candidiasis, 200 mg twice daily for 1 day
- Pityriasis versicolor, 200 mg once daily for 7 days
- Tinea corporis and tinea cruris, either 100 mg once daily for 15 days or 200 mg once daily for 7 days
- Tinea pedis and tinea manuum, either 100 mg once daily for 30 days or 200 mg twice daily for 7 days
- Onychomycosis, either 200 mg once daily for 3 months or course of 200 mg twice daily for 7 days, subsequent courses repeated after 21-day interval; fingernails 2 courses, toenails 3 courses
- Aspergillosis, 200mg twice daily
- Histoplasmosis, 200 mg 3 times daily for 3 days, then 200 mg once or twice daily
- Systemic candidiasis and cryptococcosis including cryptococcal meningitis where other antifungal drugs inappropriate or ineffective, 200 mg once daily (candidiasis 100–200 mg once daily) increased in invasive or disseminated disease and in cryptococcal meningitis to 200 mg twice daily
- Maintenance in HIV-infected patients to prevent relapse of underlying fungal infection and prophylaxis in neutropenia when standard therapy inappropriate, 200 mg once daily; increased to 200 mg twice daily if low plasma-itraconazole concentration

Or as directed by the Physician.

Storage:
Store in a cool & dry place. Protected from light & moisture.

KEEP OUT OF REACH OF CHILDREN

Manufactured By:
Healing® Pharma
Your health is our world
Healing Pharma India Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
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