

IT-wise[®]-100

(Itraconazole Capsules 100 mg)

Composition:

Each Capsule Contains:

Itraconazole (As Pellets) B.P..... 100 mg

Excipients...q.s.

Clinical Pharmacology:

Itraconazole

Ergosterol is the predominant sterol in the fungal membrane. Putative target for itraconazoles, the enzyme 14-a-demethylase is essential and is involved in the progressive removal of methyl groups from lanosterol as part of the biosynthesis of ergosterol. Itraconazole induce a profound disruption in the normal balance of sterols leading to a decrease in ergosterol content and an accumulation in methylated precursor. The Itraconazole inhibit cytochrome P450 (CYP) enzymes, which are a superfamily of haemoproteins involved in the synthesis and detoxification of compounds via hydroxylation reactions. CYP enzymes are important for the biosynthesis of sterols that are vital components of fungal cell membranes.

Indication:

- ❖ Invasive and non-invasive pulmonary aspergillosis.
- ❖ Oral and/or esophageal candidiasis.
- ❖ Chronic pulmonary histoplasmosis.
- ❖ Cutaneous and lymphatic sporotrichosis.
- ❖ Paracoccidioidomycosis.
- ❖ Chromomycosis.
- ❖ Blastomycosis

Use in Special Population:**Children:**

Not recommended.

Renal insufficiency:

Patients with renal impairment suggested no significant effect of haemodialysis or peritoneal dialysis on the pharmacokinetics of itraconazole. In moderate-to-severe uraemia AUCs were slightly reduced compared with estimates obtained from patients with normal renal function.

Hepatic insufficiency:

Patients with impaired hepatic function require assiduous monitoring.

Contraindications:

Prolongs the action of benzodiazepines, digoxin, statins and warfarin.

Precautions & Warning:

Should not be used in pregnant women. Also, in breastfeeding.

Drug interaction:

Prolongs the action of benzodiazepines, digoxin, statins and warfarin.

Adverse effect:

Can causes Nausea, vomiting, diarrhea, headache, and dizziness

Overdose:

Can causes Nausea, vomiting, diarrhea, headache, and dizziness

Dosage:

As directed by the Physician.

SCHEDULE H PRESCRIPTION DRUG-CAUTION Not to be sold by retail without the Prescription of a Registered Medical Practitioner.

Storage: Store in a cool, dry & dark place.

For Therapeutic Use.

Route of administration: Oral

Presentation: IT-WISE-100 is available as 10X10 Capsules

Marketed By :



EPIONE PHARMACEUTICALS PVT.LTD.

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