Information For the User
Itraconazole (400mg) Tablet

Itralom 400 SR Tablet

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Composition:
Each sustained release tablet contains:
• **Itraconazole I.P.** 400 mg
• **Excipients** – q.s.
• **Colour**: Approved colour used

Dosage Form:
Tablet (Sustained Release)

Therapeutic Category:
Systemic Antifungal – Triazole Class

Pharmacology & Mechanism of Action:

Itraconazole is a broad-spectrum antifungal agent that belongs to the triazole group. It inhibits the fungal cytochrome P450 enzyme 14α-demethylase, which is crucial for converting lanosterol to ergosterol, an essential component of the fungal cell membrane. This disruption leads to increased cellular permeability and inhibition of fungal growth.

Its extended-release formulation allows prolonged therapeutic levels with once-daily dosing, ensuring improved patient compliance and consistent antifungal coverage.

Indications:

• Systemic fungal infections including histoplasmosis, blastomycosis, and aspergillosis
• Onychomycosis of the fingernails or toenails due to dermatophytes and/or Candida
• Oral and esophageal candidiasis
• Tinea corporis, cruris, and pedis
• Prophylaxis of fungal infections in immunocompromised patients

Dosage and Administration:

• **Usual adult dose**: One tablet (400 mg) once daily or as directed by the physician
• To be taken **after a full meal** to enhance absorption
• Duration of therapy depends on the indication and clinical response
• Avoid antacids within 2 hours of dosing to prevent reduced absorption

Contraindications:

• Known hypersensitivity to itraconazole or any component of the formulation
• Concomitant administration with drugs that are metabolized by CYP3A4 and may prolong QT

interval (e.g., cisapride, pimozide, quinidine)
• History of congestive heart failure or ventricular dysfunction unless benefit outweighs risk

Warnings and Precautions:

• Monitor hepatic function during prolonged therapy; discontinue if signs of liver dysfunction appear
• Use with caution in patients with cardiac disease, renal impairment, or electrolyte disturbances
• Not recommended during pregnancy unless life-threatening infection
• Women of childbearing potential should use effective contraception during therapy and for 2 months after stopping

Drug Interactions:

• Potent inhibitor of CYP3A4 – may increase plasma concentrations of drugs metabolized by this enzyme
• Antacids, H2 blockers, and proton pump inhibitors reduce bioavailability of itraconazole
• Increased risk of toxicity when combined with statins, calcium channel blockers, and certain benzodiazepines
• Rifampicin and phenytoin reduce itraconazole levels; avoid concurrent use

Adverse Effects:

• Common: Nausea, vomiting, abdominal pain, headache
• Less common: Elevated liver enzymes, rash, edema
• Rare: Hepatotoxicity, peripheral neuropathy, hypersensitivity reactions including anaphylaxis

Overdose:

Symptoms include gastrointestinal discomfort, headache, and potential hepatotoxicity. Treatment is symptomatic and supportive. Itraconazole is not significantly removed by hemodialysis.

Storage:

Store below 25°C in a cool, dry place
Protect from light and moisture
Keep out of reach of children

Manufactured in India for:

Cafoli™
LIFECARE

Cafoli Lifecare Pvt. Ltd.
(An ISO 9001: 2015 Certified Co.)
Plot no.: 367-FF, Industrial Area Phase-I,
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