

Information For the User  
Itraconazole (200mg) + Terbinafine (250mg)

# Italom TRB Tablet

**Name of the Product:** Italom TRB Tablet

**Composition:** Each film-coated tablet contains:

- Itraconazole IP ... 200 mg
- Terbinafine Hydrochloride IP (eq. to Terbinafine base) ... 250 mg

**Dosage Form:** Tablet

**Description:**

Italom TRB Tablet combines two potent systemic antifungal agents—Itraconazole and Terbinafine. Itraconazole is a triazole antifungal that inhibits ergosterol synthesis, an essential component of fungal cell membranes. Terbinafine is an allylamine antifungal that interferes with squalene epoxidase, disrupting fungal cell membrane integrity. This dual-action combination offers broad-spectrum coverage against dermatophytes, yeasts, and molds.

**Indications:**

- Refractory or extensive dermatophytosis
- Onychomycosis (fungal nail infection)
- Tinea corporis, Tinea cruris, Tinea pedis
- Seborrheic dermatitis (systemic treatment)
- Fungal infections unresponsive to monotherapy

**Mechanism of Action:**

- **Itraconazole** inhibits cytochrome P450-dependent 14 $\alpha$ -demethylase enzyme, blocking ergosterol synthesis and increasing fungal cell membrane permeability.
  - **Terbinafine** inhibits squalene epoxidase, leading to ergosterol depletion and intracellular squalene accumulation, which is toxic to fungi.
- This dual mechanism ensures better fungal eradication and lowers the risk of resistance.

**Dosage and Administration:**

- **Usual Adult Dose:** One tablet once daily or as prescribed by the physician
- Should be taken after a full meal for optimal absorption
- Duration of therapy varies depending on infection site and severity

**Contraindications:**

- Hypersensitivity to Itraconazole, Terbinafine, or any excipients
- Severe hepatic or renal impairment
- Concurrent use with certain drugs like quinidine, dofetilide, or cisapride

**Warnings and Precautions:**

- Monitor liver function during prolonged use
- Use with caution in patients with cardiac dysfunction
- Avoid alcohol and hepatotoxic drugs concurrently
- Not recommended during pregnancy and lactation unless clearly indicated

**Adverse Effects:**

- Nausea, vomiting, abdominal pain
- Headache, dizziness
- Elevated liver enzymes
- Rash or skin reactions
- Rarely, hepatotoxicity or hypersensitivity reactions

**Storage:**

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

**Schedule:**

Schedule H drug – to be sold by retail on the prescription of a Registered Medical Practitioner only.

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

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Panchkula-134113

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