

# Italom SB 65 Capsule

## Information for the Use

### Itraconazole 65mg Capsule

#### Composition:

Each capsule contains:

- Itraconazole: 65 mg

#### Indications:

Itraconazole 65mg capsule is an antifungal medication used for the treatment and prevention of various fungal infections, such as:

- **Systemic Fungal Infections:** Including aspergillosis, histoplasmosis, and blastomycosis.
- **Candidiasis:** For oral, esophageal, or vaginal candidiasis.
- **Dermatophytosis:** Skin fungal infections, including tinea corporis, tinea cruris, and tinea pedis.
- **Onychomycosis (Fungal Nail Infections):** Treats fungal infections affecting nails.
- **Fungal Prophylaxis:** Prevents fungal infections in immunocompromised patients (e.g., undergoing chemotherapy or with HIV/AIDS).

#### Mechanism of Action:

Itraconazole works by inhibiting the production of ergosterol, a key component of fungal cell membranes. This disruption weakens the cell membrane, leading to fungal cell death and inhibition of fungal growth.

#### Dosage and Administration:

- **Adults:**
  - The standard dose depends on the type and severity of the infection. The usual dose is 65 mg two to

three times daily, or as prescribed by the healthcare provider.

- For onychomycosis or systemic infections, higher doses or prolonged treatment duration may be required.
- **Children:**
  - Use in pediatric patients should be determined by a healthcare professional based on weight and the specific infection.

#### Administration:

- Take the capsule with food to enhance absorption.
- Swallow the capsule whole with a glass of water.
- Avoid taking itraconazole with antacids, as these can reduce its absorption. Separate doses of antacids and itraconazole by at least 2 hours.

#### Contraindications:

- **Allergy:** Known hypersensitivity to itraconazole or any azole antifungal.
- **Severe Liver Disease:** Should not be used in patients with active or severe liver dysfunction.
- **Heart Conditions:** Contraindicated in patients with a history of congestive heart failure.
- **Drug Interactions:** Avoid concurrent use with cisapride, pimozide, quinidine, or dofetilide due to the risk of life-threatening arrhythmias.

#### Precautions:

- **Liver Function:** Regular monitoring of liver enzymes is recommended, especially during prolonged use.

- **Heart Failure Risk:** Use with caution in patients with pre-existing heart conditions, as itraconazole may exacerbate symptoms.
- **Pregnancy and Breastfeeding:**
  - **Pregnancy:** Not recommended unless absolutely necessary (Category C).
  - **Breastfeeding:** Use with caution; itraconazole can pass into breast milk.

#### **Possible Side Effects:**

##### **Common side effects:**

- Nausea, vomiting, and abdominal discomfort
- Headache or dizziness
- Skin rash or itching
- Loss of appetite or fatigue

##### **Serious side effects:**

- **Liver toxicity:** Symptoms include jaundice, dark urine, or abdominal pain.
- **Heart-related issues:** Shortness of breath, swelling, or sudden weight gain.
- **Severe allergic reactions:** Difficulty breathing, facial swelling, or severe rash.
- **Severe skin reactions:** Blistering or peeling of the skin.

#### **Drug Interactions:**

**Itraconazole can interact with numerous drugs:**

- **Statins (e.g., simvastatin, atorvastatin):** Increased risk of muscle damage (myopathy).
- **Anticoagulants (e.g., warfarin):** Increased bleeding risk.
- **CYP3A4 inducers (e.g., rifampin, carbamazepine):** May reduce itraconazole levels, decreasing its effectiveness.
- **Antacids or Proton Pump Inhibitors:** Reduce itraconazole absorption; take itraconazole at least 2 hours before or after these medications.

#### **Storage:**

- Store at 15°C to 30°C, in a cool and dry place, away from direct sunlight and moisture.
- Keep out of the reach of children.

---

**Note:** Always use this medication under the supervision of a healthcare provider. Adhere to the prescribed dosage and treatment duration. If you experience severe side effects or unusual symptoms, seek medical attention immediately.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,  
Panchkula-134113

TM: Trademark Applied for