

**Name of Medicinal Product:** Fixtral SB® (Itraconazole Capsules 100 mg Supra-Bioavailable Formulation)

**Dosage Form and Strength:** Each Hard Gelatin Capsule Contains: Itraconazole Ph.Eur.... 100mg

**Directions for use:** For oral administration only. **Therapeutic Indications:** Systemic Aspergillosis and Candidosis,

Cryptococcosis, Sporotrichosis, Paracoccidioidomycosis, Blastomycosis and other rarely occurring systemic or topical mycosis. **Dosage and Administration:** Can be taken with or without food. 1 capsule of

100mg of suprabioavailable Itraconazole is equivalent to 200 mg of conventional Itraconazole. For

Aspergillosis, Candidosis, Non-meningeal Cryptococcosis, Blastomycosis, Paracoccidioidomycosis 100 mg

once daily is recommended dose. For Cryptococcosis meningitis 100 mg b.i.d is recommended. For topical

mycosis 100 mg once daily dose in indications of Vulvovaginal candidosis, Pityriasis versicolor, Tinea

corporis & Tinea cruris, Onychomycosis. Additional Dose & Duration of therapy is as per clinician's

discretion. **Use in Special Populations: Pediatric population:** Clinical Data on Use in pediatric population

are limited **Older patients:** Dose adjustment to be considered as per hepatic, renal & cardiac function

**Renal insufficiency / dialysis:** Oral bioavailability is reduced in patients of renal insufficiency **Hepatic**

**impairment:** Clinical Data on Use in hepatic impaired populations are limited **Adverse events:** Headache,

abdominal pain & nausea are most common adverse effects Further information available upon request.

**Contraindications:** Not to be used in hypersensitive to any of active substances or excipients.

Further information available upon request.

Date: 1<sup>st</sup> March 2023