ITRACLAR SB

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for ITRACLAR SB (Itraconazole Capsules**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Itraconazole inhibits fungal 14α-demethylase, resulting in a depletion of ergosterol and disruption of membrane synthesis by fungi.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Itraconazole Capsules are contra-indicated in patients with known hypersensitivity to itraconazole or to any of the excipients, Co-administration of a number of CYP3A4 substrates is contraindicated with Itraconazole Capsules. Increased plasma concentrations of these drugs, caused by co-administration with itraconazole, may increase or prolong both therapeutic and adverse effects to such an extent that a potentially serious situation may occur. For example, increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of torsade de pointes, a potentially fatal arrhythmia, Itraconazole Capsules should not be administered to patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF except for the treatment of life-threatening or other serious infections, Itraconazole Capsules must not be used during pregnancy except for life-threatening cases, Women of childbearing potential taking Itraconazole Capsules should use contraceptive precautions. Effective contraception should be continued until the menstrual period following the end of Itraconazole Capsules therapy.

WARNINGS & PRECAUTIONS: *Cardiac effects:* Itraconazole has been shown to have a negative inotropic effect and Itraconazole Capsules has been associated with reports of congestive heart failure. Itraconazole should not be used in patients with congestive heart failure or with a history of congestive heart failure unless the benefit clearly outweighs the risk. Calcium channel blockers can have negative inotropic effects which may be additive to those of itraconazole. *Hepatic effects:*Very rare cases of serious hepatotoxicity, including some cases of fatal acute liver failure, have occurred with the use of Itraconazole Capsules. *Reduced gastric acidity*: Absorption of itraconazole from Itraconazole Capsules is impaired when gastric acidity is reduced. *Paediatric population:* Clinical data on the use of Itraconazole Capsules in paediatric patients is limited. *Use in Elderly:* Itraconazole Capsules in these patients only if it is determined that the potential benefit outweighs the potential risks. *Renal impairment:* The exposure of itraconazole may be lower in some patients with renal insufficiency. Caution should be exercised. *Hearing Lossl:* Transient or permanent hearing loss has been reported in patients receiving treatment with itraconazole. *Immunocompromised patients:*In some immunocompromised patients (e.g., neutropenic, AIDS or organ transplant patients), the oral bioavailability of Itraconazole Capsules may be decreased. *Patients with AIDS:* In patients with AIDS having received treatment for a systemic fungal infection such as sporotrichosis, blastomycosis, histoplasmosis or cryptococcosis (meningeal or nonmeningeal) and who are considered at risk for relapse, the treating physician should evaluate the need for a maintenance treatment. *Neuropathy:* If neuropathy occurs which may be attributable to Itraconazole Capsules, the treatment should be discontinued. *Disorders of Carbohydrate Metabolism*,

Cross-resistance: In systemic candidosis, if fluconazole-resistant strains of Candida species are suspected, it cannot be assumed that these are sensitive to itraconazole, hence their sensitivity should be tested before the start of Itraconazole therapy. *Interchangeability*: It is not recommended that itraconazole capsules and itraconazole oral solution be used interchangeably. *Interaction Potential:* Coadministration of specific drugs with itraconazole may result in changes in efficacy of itraconazole and/or the coadministered drug, life-threatening effects and/or sudden death.

DRUG INTERACTION: Itraconazole is mainly metabolised through CYP3A4. Other substances that either share this metabolic pathway or modify CYP3A4 activity may influence the pharmacokinetics of itraconazole. Similarly, itraconazole may modify the pharmacokinetics of other substances that share this metabolic pathway. Itraconazole is a potent CYP3A4 inhibitor and a P glycoprotein inhibitor. When using concomitant medication, it is recommended that the corresponding label be consulted for information on the route of metabolism and the possible need to adjust dosages. Drugs that may decrease itraconazole plasma concentrations: e.g. acid neutralising medicines such as aluminum hydroxide, or acid secretion suppressors such as H2-receptor antagonists and proton pump inhibitors It is recommended that itraconazole be administered with an acidic beverage (such as nondiet cola) upon co-treatment with drugs reducing gastric acidity. Coadministration of itraconazole with potent enzyme inducers of CYP3A4 may decrease the bioavailability of itraconazole and hydroxy-itraconazole to such an extent that efficacy may be largely reduced. e.g. Antibacterials, Anticonvulsants, Antivirals, Drugs that may increase itraconazole plasma concentrations: ciprofloxacin, clarithromycin, erythromycin, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, indinavir, Drugs that may have their plasma concentrations increased by itraconazole , Drugs that may have their plasma concentrations decreased by itraconazole Coadministration of itraconazole with the NSAID meloxicam may decrease the plasma concentrations of meloxicam.

ADVERSE REACTIONS: Granulocytopenia, Thrombocytopenia**,** Anaphylactoid reaction**,** Hyperglycaemia, Hyperkalaemia, Hypokalaemia, Hypomagnesaemia, Confusional state**,** Peripheral neuropathy*, Dizziness, Somnolence, Tremor**,** Cardiac failure, Left ventricular failure, Tachycardia**,** Hypertension, Hypotension**,** Pulmonary oedema, Dysphonia, Cough, Gastrointestinal disorder**,** Hepatic failure*, Hepatitis, Jaundice**,** Rash erythematous, Hyperhidrosis**,** Myalgia, Arthralgia**,** Renal impairment, Urinary incontinence**,** Generalised oedema, Face oedema, Chest pain, Pyrexia, Pain, Fatigue, Chills, Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood alkaline phosphatase increased, Blood lactate dehydrogenase increased, Blood urea increased, Gamma-glutamyltransferase increased, Hepatic enzyme increased, Urine analysis abnormal.

Manufactured by:
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(Additional information is available on request)