ITRACLAR/TRICUTIS

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ITRACLAR/TRICUTIS [Itraconazole Capsules I.P.]
[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.

INDICATIONS: *ITRACLAR/TRICUTIS 100*: It is indicated for Systemic aspergillosis and candidas cryptococcosis, sporotrichosis, paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses. *ITRACLAR/TRICUTIS 200*: It is indicated for treatment of onychomycosis of the toenail due to Trichophyton rubrum or T. mentagrophytes in non-immunocompromised patients.

DOSAGE AND ADMINISTRATION: Itraconazole capsule is for oral administration and can be taken with or without food.

CONTRAINDICATION: Itraconazole Capsules are contraindicated 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: Caution should be used in prescribing Itraconazole capsules to patients with hypersensitivity to other azoles. 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. Such patients should be informed of the signs and symptoms of congestive heart failure, should be treated with caution, and should be monitored for signs and symptoms of congestive heart failure during treatment; if such signs or symptoms do occur during treatment, Itraconazole should be discontinued. Caution should be exercised when co-administering itraconazole and calcium channel blockers due to an increased risk of congestive heart failure. It is recommended that liver function monitoring be done in patients with pre-existing hepatic function abnormalities or those who have experienced liver toxicity with other medications.

DRUG INTERACTIONS: Itraconazole is mainly metabolised through CYP3A4. Other substances that either share this metabolic pathway or modify CYP3A4 activity may influence the pharmacokinetics of itraconazole. Drugs that reduce the gastric acidity (e.g. acid neutralising medicines such as aluminium hydroxide, or acid secretion suppressors such as H2-receptor antagonists and proton pump inhibitors) impair the absorption of itraconazole from itraconazole capsules. Therefore, administration of potent enzyme inducers of CYP3A4 with itraconazole is not recommended. Potent inhibitors of CYP3A4 may increase the bioavailability of itraconazole. Itraconazole and its major metabolite, hydroxy-itraconazole, can inhibit the metabolism of drugs metabolised by CYP3A4 and can inhibit the drug transport by P-glycoprotein, which may result in increased plasma concentrations of these drugs and/or their active metabolite(s) when they are administered with itraconazole. Coadministration of itraconazole with the

NSAID meloxicam may decrease the plasma concentrations of meloxicam.

ADVERSE REACTIONS: Sinusitis, upper respiratory tract infection, rhinitis, leukopenia, hypersensitivity, anaphylactic reaction, angioneurotic oedema, serum sickness, hypertriglyceridemia, headache, hypoaesthesia, paraesthesia, dysgeusia, visual disturbance (including diplopia and blurred vision), tinnitus, transient or permanent hearing loss, congestive heart failure, dyspnoea, abdominal pain, nausea, vomiting, diarrhoea, constipation, dyspepsia, flatulence, pancreatitis, hepatic function abnormal, serious hepatotoxicity, hyperbilirubinaemia, urticaria, rash, pruritus, toxic epidermal necrolysis, stevens-johnson syndrome, acute generalised exhanthematous pustulosis, erythema multiforme, exfoliative dermatitis, leukocytoclastic vasculitis, alopecia, photosensitivity, pollakiuria, menstrual disorders, erectile dysfunction, oedema, blood creatine phosphokinase increased. granulocytopenia, thrombocytopenia, hyperglycaemia, hyperkalaemia, hypokalaemia, hypomagnesaemia, confusional state, peripheral neuropathy, dizziness, somnolence, tremor, cardiac failure, left ventricular failure, tachycardia, hypertension, hypotension, pulmonary oedema, dysphonia, cough, hepatitis, jaundice, 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.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/ITRACLAR/TRICUTIS 100, 200 mg/DEC-2025/01/ABPI

(Additional information is available on request)