

SY SC A N

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

Abbreviated Prescribing information for **SYSCAN** [Fluconazole 150mg and 200mg hard gelatin capsule] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Fluconazole is a triazole antifungal agent. Its primary mode of action is the inhibition of fungal cytochrome P-450-mediated 14 alpha-lanosterol demethylation, an essential step in fungal ergosterol biosynthesis. The accumulation of 14 alpha-methyl sterols correlates with the subsequent loss of ergosterol in the fungal cell membrane and may be responsible for the antifungal activity of fluconazole. Fluconazole has been shown to be more selective for fungal cytochrome P-450 enzymes than for various mammalian cytochrome P-450 enzyme systems.

INDICATION:

SYSCAN 150:

It is indicated for treatment of vaginitis due to trichomoniasis and vulvo vaginal Candidiasis in women.

SYSCAN 200:

It is indicated for treatment of systemic candidiasis, mucosal candidiasis and cryptococcosis and prevention of fungal infections in patients with malignancy.

DOSAGE AND ADMINISTRATION: Hard gelatin capsule, fluconazole 150 mg and 200mg. The Syscan medicine must be taken as directed by physician. Fluconazole may be administered either orally (Capsules and powder for oral suspension) or by intravenous infusion (Solution for infusion), the route being dependent on the clinical state of the patient. On transferring from the intravenous to the oral route, or vice versa, there is no need to change the daily dose. The capsules should be swallowed whole and independent of food intake.

CONTRAINDICATION: Hypersensitivity to the active substance, to related azole substances, or to any of the excipients listed. Co-administration of terfenadine is contra-indicated in patients receiving fluconazole at multiple doses of 400 mg per day or higher based upon results of a multiple dose interaction study. Co-administration of other medicinal products known to prolong the QT interval and which are metabolised via the cytochrome P450 (CYP) 3A4 such as cisapride, astemizole, pimozone, quinidine and erythromycin are contra-indicated in patients receiving fluconazole.

WARNINGS & PRECAUTIONS: Use cautiously or stop the fluconazole in patient with tinea capitis, cryptococcosis, deep endemic mycoses, renal and liver dysfunction, prolongation of the QT interval, potentially proarrhythmic conditions, halofantrine, dermatological reactions, hypersensitivity and co- administration of terfenadine.

DRUG INTERACTIONS: Cisapride, terfenadine, astemizole, pimozone, quinidine, erythromycin, halofantrine, rifampicin, alfentanil, amitriptyline, nortriptyline, amphotericin B, anticoagulants, benzodiazepines (short acting), i.e. midazolam, triazolam, carbamazepine, calcium channel blockers, celecoxib, cyclophosphamide, fentanyl, HMG-coA reductase inhibitors, immunosuppressors (i.e. ciclosporin, everolimus, sirolimus and tacrolimus), everolimus, sirolimus, tacrolimus, losartan, methadone, NSAIDs, phenytoin, prednisone, rifabutin, saquinavir, sulfonyleureas, theophylline, vinca alkaloids, vitamin A, voriconazole, zidovudine, azithromycin, oral contraceptives and ivacaftor.

ADVERSE REACTIONS: Anaemia, decreased appetite, somnolence, insomnia, headache seizures, paraesthesia, dizziness, taste perversion, vertigo, abdominal pain, vomiting, diarrhoea, nausea, constipation, dyspepsia, flatulence, dry mouth, alanine aminotransferase increased, aspartate aminotransferase increased, liver failure, low blood potassium, blood alkaline phosphatase increased, cholestasis, jaundice, bilirubin increased, rash, drug eruption, urticaria, pruritus, hair loss, increased sweating, myalgia, fatigue, malaise, asthenia, red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes, lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding, swelling of eyelids, face or lips, sudden wheezing, difficulty in breathing or tightness in the chest, itching all over the body reddening of the skin or itchy red spots and fever.

MARKETED BY:



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(Additional information is available on request)