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Full prescribing information available on request:



the drug discovery company

B-2340 Beerse, Belgium

Prescribing information

Presentation: white, flat, half scored uncoated tablets marked "Janssen" on one side and K/200 on the reverse. Each tablet contains 200 mg ketoconazole

Uses: **Happrals** an orally active antimycotic for the treatment in adults of vaginal candidosis, superficial and systemic mycoses including dermatophyte and yeast infections of the malist, past infections of the mouth and CI.-tract. Also maintenance treatment of systemic mycoses and chronic mucocutaneous candidosis and prophytaxis in "at risk" patients. In children: systemic mycoses and severe local infections where prejudutopolal treatment has failed.

Side-effects, precautions, contraindications: contra-indicated in pregnancy. For maximal absorption **Natural** should be taken with meals. The use of agents which reduce gastric acidity faint-cholinerig dicryas, antacids. H., photokers should be avoided and, if indicated such drugs should be taken not leg than two nours after **Natural** shauses, skin rash, headache and pruritus may occasionally be observed after attention linker function tests the occurred in patients on seteronaxolo; these changes may be translend; cases of hepatitis have beer reported with an incidence of about 1 per 10,000 patients. Some of these may represent an idiosyncratic adverse reaction to the drug This should be borned in mind in patients on long-term theraby. If a patient develops laundice of any symptom suggestive of hepatitis treatment with ketoconazole shople do stopped. Mild asymptomatic increases of liver enzyme levels, on the other hand, do not necessitate discontinuation of the treat-plent. Retoconazole, when given together with cyclosporin A. It is important that bood levels of cyclosporin A. It is important that bood levels of cyclosporin A are monitored if the two drugs are given committantly. Retoconazole 200 mg once daily produces a translent decrease in plasma levels of testosterone. During long term therapy at this dose, testosterone levels are usually not significantly different from controls in rare instances, synaecomastic has been reported.

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