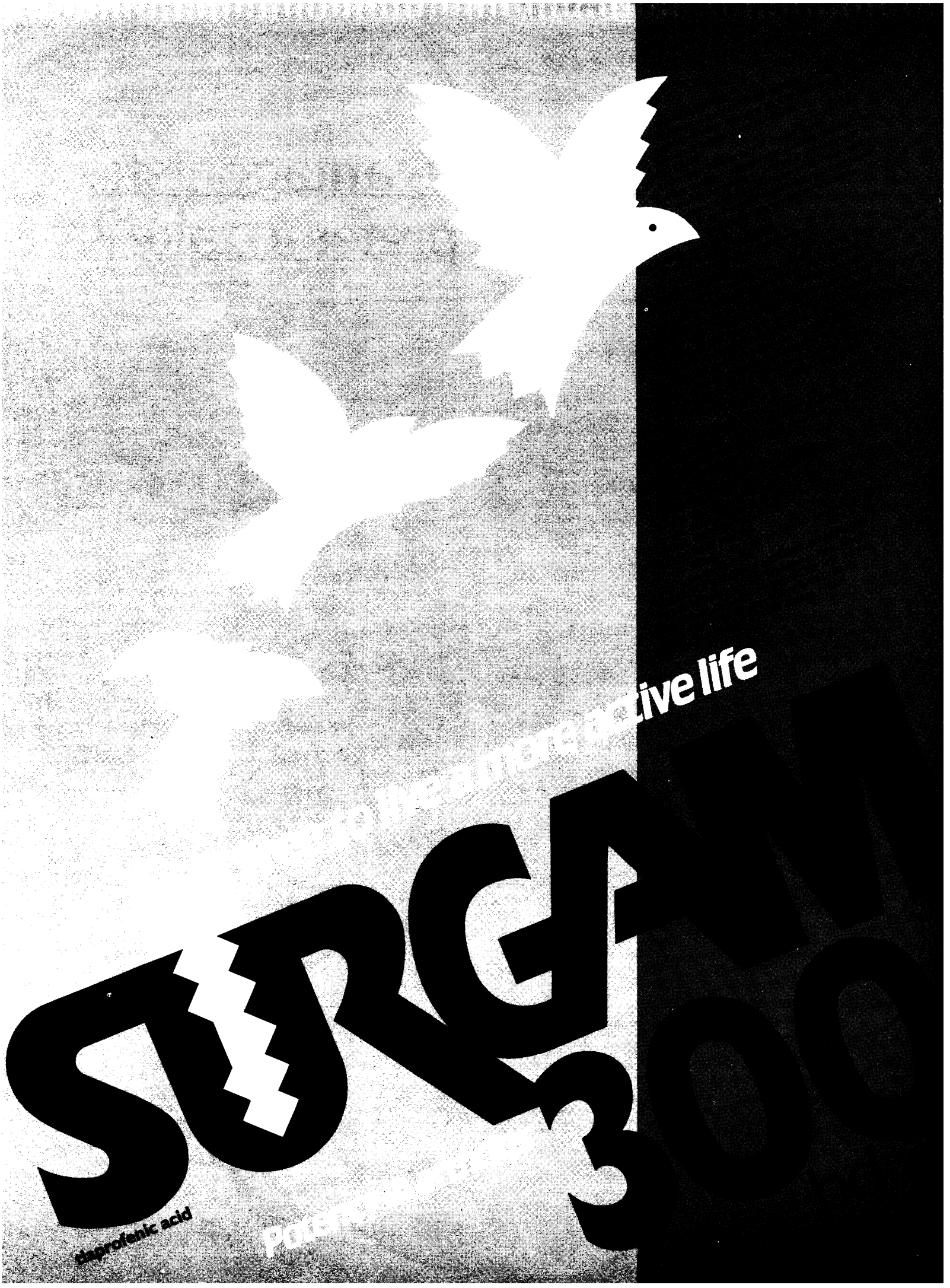
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TRADEMARK

Nizoral

(ketoconazole) (tablets)

over 3 million prescriptions world-wide:

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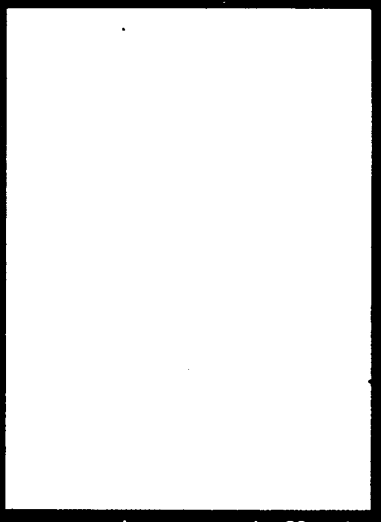

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the drug discovery company

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: **Nizoral** is an orally active antimycotic for the treatment in adults of vaginal candidosis, superficial and systemic mycoses including dermatophyte and yeast infections of the skin, hair and nails, yeast infections of the mouth and G.I.-tract. Also maintenance treatment of systemic mycoses and chronic mucocutaneous candidosis and prophylaxis in "at risk" patients. In children: systemic mycoses and severe local infections where previous topical treatment has failed.

Side-effects, precautions, contra-indications: contra-indicated in pregnancy. For maximal absorption **Nizoral** should be taken with meals. The use of agents which reduce gastric acidity (anti-cholinergic drugs, antacids, H_2-blockers) should be avoided and, if indicated, such drugs should be taken not less than two hours after **Nizoral**. Nausea, skin rash, headache and pruritus may occasionally be observed. Alterations in liver function tests have occurred in patients on ketoconazole; these changes may be transient. Cases of hepatitis have been 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 borne in mind in patients on long-term therapy; if a patient develops jaundice or any symptoms suggestive of hepatitis, treatment with ketoconazole should be stopped. Mild asymptomatic increases of liver enzyme levels, on the other hand, do not necessitate discontinuation of the treatment. Ketoconazole, when given together with cyclosporin A results in increased blood levels of cyclosporin A. It is important that blood levels of cyclosporin A are monitored if the two drugs are given concomittantly. Ketoconazole 200 mg once daily produces a transient 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, gynaecomastia has been reported.

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ADALAT RETARD

ANTIHYPERTENSIVE
WITH CARDIOPROTECTIVE EFFECT

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