

Nizoral

TRADE MARK

ketoconazole

Oral therapy for all common fungal infections

Vaginal candidosis:	In all dermatological and in systemic fungal infections:
2 tablets once daily (with food) for 5 days	1 tablet daily (with food) until complete symptomatic and mycological cure is obtained

Not all indications are as yet approved in all countries.

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, H₂ 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.



Janssen Pharmaceutica
B-2340 Beerse, Belgium

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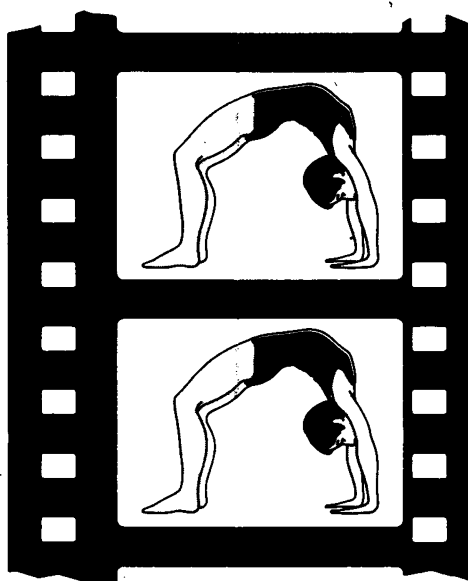
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