

TRADEMARK

# Nizoral

(ketoconazole)

(tablets)

# over 3 million prescriptions world-wide:

**the new beginning  
in antifungal therapy.**



Doctors and patients around the world are discovering the modern simplicity of **Nizoral** oral therapy. Common but problematic fungal infections can now be treated effectively and conveniently. Typically, in recurrent *Candida* vaginitis, 2 oral tablets once daily for 5 days is all it takes today to effectively cure the problem.

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**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 GI-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<sub>2</sub>-blockers) should be avoided and, if indicated, such drugs should be taken no 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 concomitantly. 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.

# Claforan

cephalosporin

## Prescribing Information

**Presentation** Vials containing 500mg, 1g or 2g of cefotaxime sodium. **Indications** Infections before identification of the organism. Infections caused by bacteria of established sensitivity, including chest infections, septicaemia, urinary tract infections, soft tissue infections, obstetric and gynaecological infections, bone and joint infections, meningitis, gonorrhoea. **Dosage** Claforan is administered i.m. or i.v. **Adults:** Usually 2-6g daily (see full prescribing information). For infections caused by sensitive *Pseudomonas* spp., doses of more than 6g daily are usually required. **Children:** 100-150mg/kg/day in 2 to 4 divided doses. Up to 200mg/kg/day may be given in very severe infections. **Neonates:** 50mg/kg body weight daily in 2 to 4 equally divided doses. In cases of severe infection, divided daily doses of 150-200mg/kg have been given. **Dosage in renal impairment** Reduced dosage is only required in severe renal failure (GFR<5ml/min = serum creatinine approx. 751  $\mu$ mol/l) when, after an initial loading dose of 1g, the daily dose is halved without change in frequency of dosing. **Contra-Indications** Known allergy to cephalosporins. **Precautions** Cephalosporin antibiotics may usually be given safely to patients who

are hypersensitive to penicillins, although cross reactions have been reported. Special care is indicated in patients who have had an anaphylactic response to penicillin. Patients with severe renal dysfunction — see previous. Cephalosporin antibiotics at high dosage should be given with caution to patients receiving aminoglycoside antibiotics or potent diuretics such as frusemide. At recommended doses, enhancement of nephrotoxicity is unlikely with Claforan. A false-positive reaction to glucose may occur with reducing substances. Claforan should not be mixed in the syringe with aminoglycoside antibiotics. The safety of Claforan in human pregnancy has not been established. **Side effects** Adverse reactions are rare and generally mild and transient, but include diarrhoea (pseudomembranous colitis has been rarely reported), candidiasis, rashes, fever, eosinophilia, leukopenia, transient rises in liver transaminase and alkaline phosphatase, transient pain at the site of injection and phlebitis. **Product licence holder** and number Roussel Laboratories Ltd., Broadwater Park, North Orbital Road, Uxbridge, Middlesex UB9 5HP. 0109/0074. **Package quantities and basic N.H.S. price** Vials of 500mg, 1g and 2g in packs of 10. One gram vial £4.95. **Date of preparation** November 1984.

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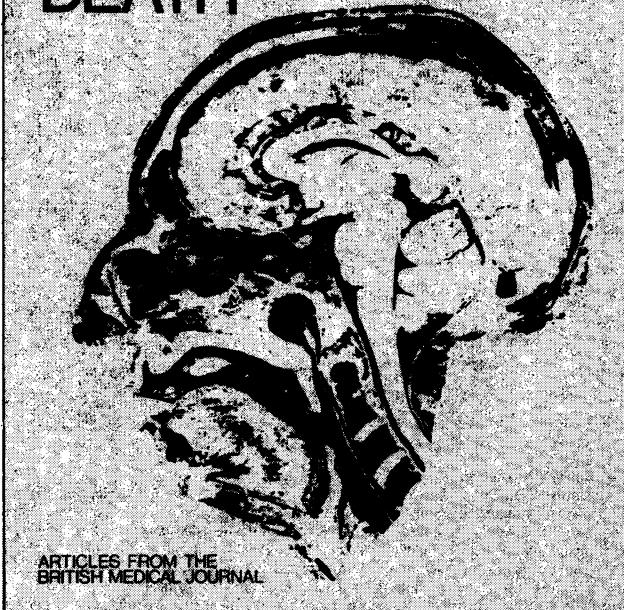
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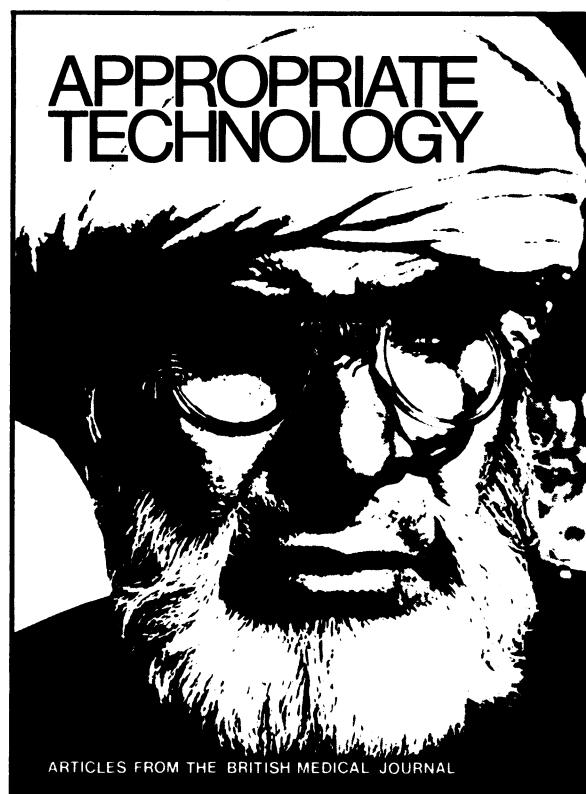
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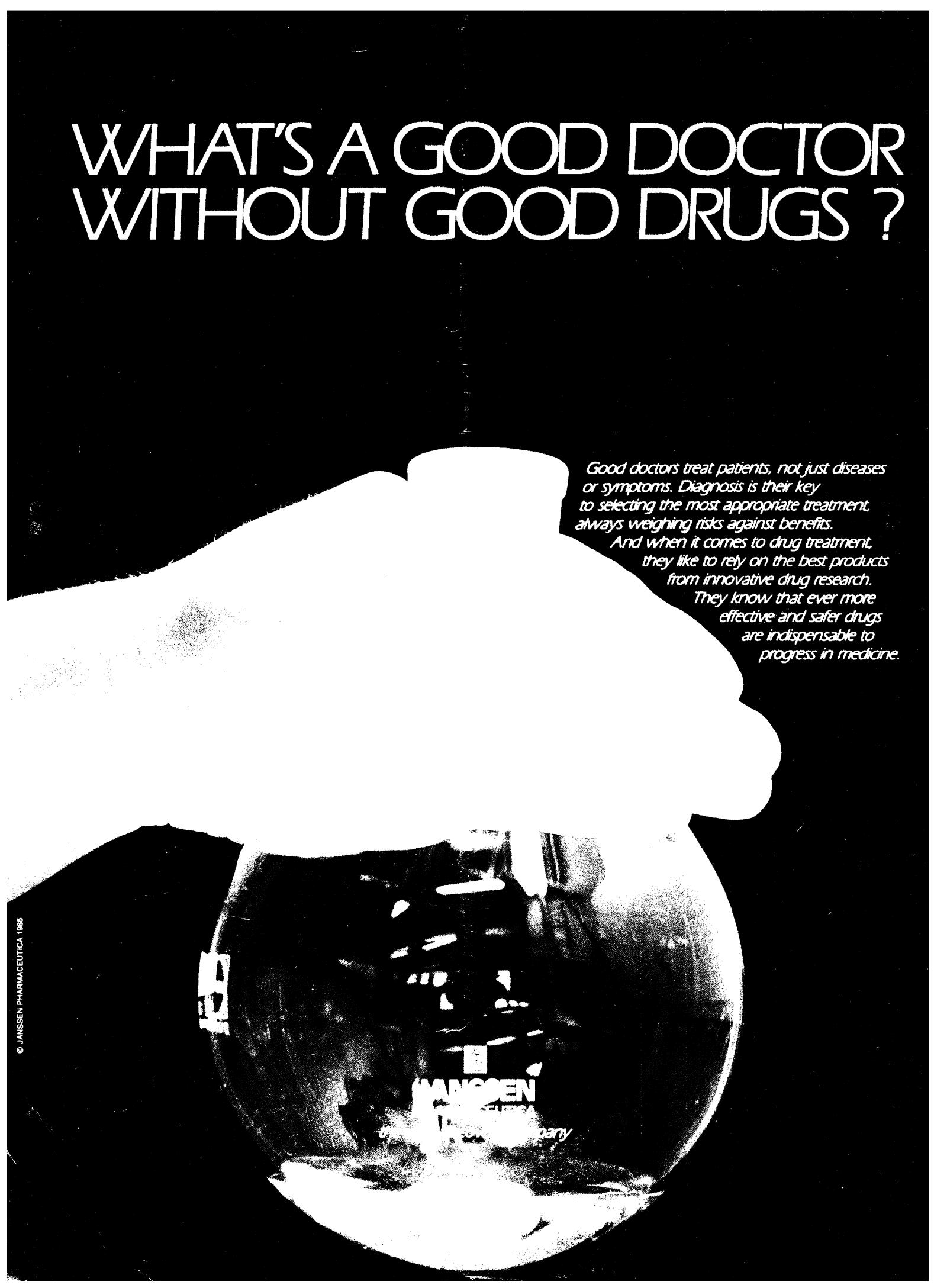
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