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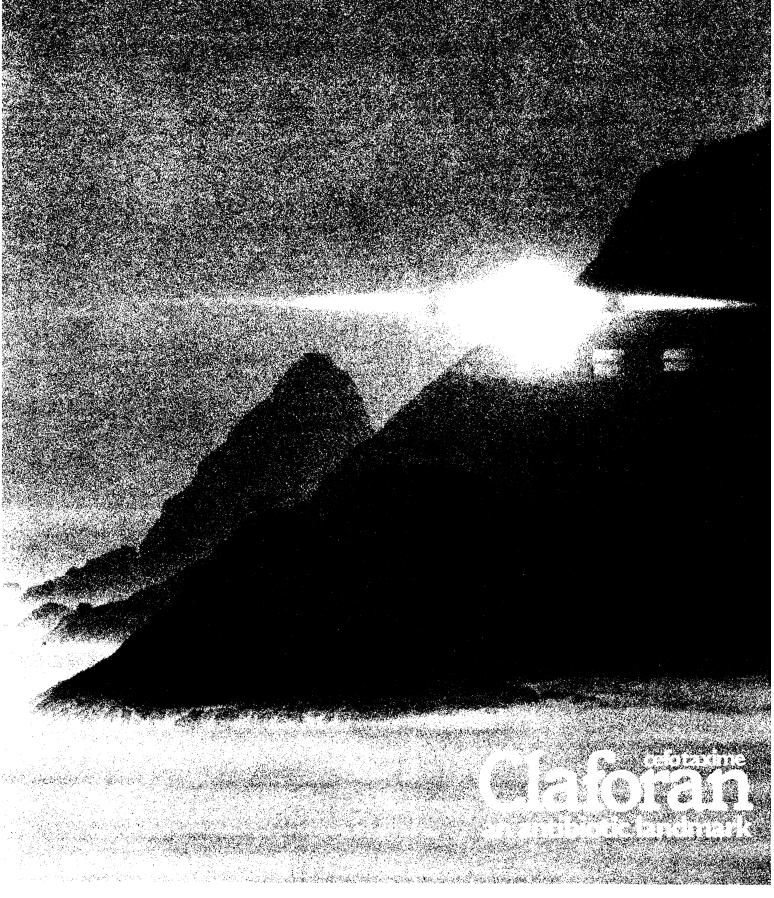
B-2340 Beerse, Belgium

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/ksterongrade.

Uses: Nitorials an orally active antimycotic for the treatment in adults of vaginal candidosis, superficial and systemic mycoses including dermatophyly and veast infections of the world and 6-L-tract. Also maintenance treatment of systemic mycoses and chronic mucocutaneous candidosis and prophylaxis in at risk, patients, in children, systemic mycoses and chronic mucocutaneous candidosis and prophylaxis in at risk, patients, in children, systemic mycoses and chronic mucocutaneous candidosis and prophylaxis in at risk, patients, in children, systemic mycoses and chronic mucocutaneous candidosis.

Side effects, precautions, contra-indications: contra-indicated in pregnancy. For maximal absorption Natorial should be taken with meals. The use of agents which reduce quastric acidity canti-cholinergic drugs, antacids. H<sub>2</sub>-blockers should be avoided and, if indicated such drugs should be taken not less than two hours after Natorial Nausea skin rash headache and pruritus may occasionally be observed atterations inliner function netsts have occurred in patients on Netconardie these changes may be transient, cases of heads tis 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 borner in mind in patients on long-term therrapy if a patient develops jaundice or any symptoms suggestive of hepatitis treatment with retoconazole should be stopped. Mild asymptomatic increases of liver enzyme levels, on the other hand, do not necessificated discontinuation of the treatment. Retoconazole, 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 concomittantiv. Retoconazole 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, synaecomastia has been reported.



### 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 µmol/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 (pseudomembraneous colitis has been rarely reported), candidiasis, rashes, fever, eosinophilla, leukopenia, transient risen liver transaminase and alkaline phosphatase, transient risen that in the site of injection and phlebitis. Product Ilcence 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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