

In vaginal candidosis:

Nizoral

TRADEMARK

ketoconazole

*the elegant way
to treat an inelegant problem*



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for 5 days
is all it takes
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to effectively
cure
the problem**

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oral convenience improves patient compliance and so reduces the chance of relapse.

Presentation: white, flat, half-scored uncoated tablets marked "Janssen" on one side and K/200 on the reverse. Each tablet contains 200 mg ketoconazole. **Dosage** (for vaginal candidosis only): two tablets (400 mg) once daily for 5 days. For maximal absorption Nizoral should be taken with meals. Nizoral is contra-indicated in pregnancy. **Precautions:** 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 2 hours after Nizoral. 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. **Side-effects:** 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. **Full prescribing information available on request.**

References:

Tooley, et al.: The Practitioner 229, 655 (1985)
Benussi, et al.: Curr. Ther. Res. 31(4), 511 (1982)



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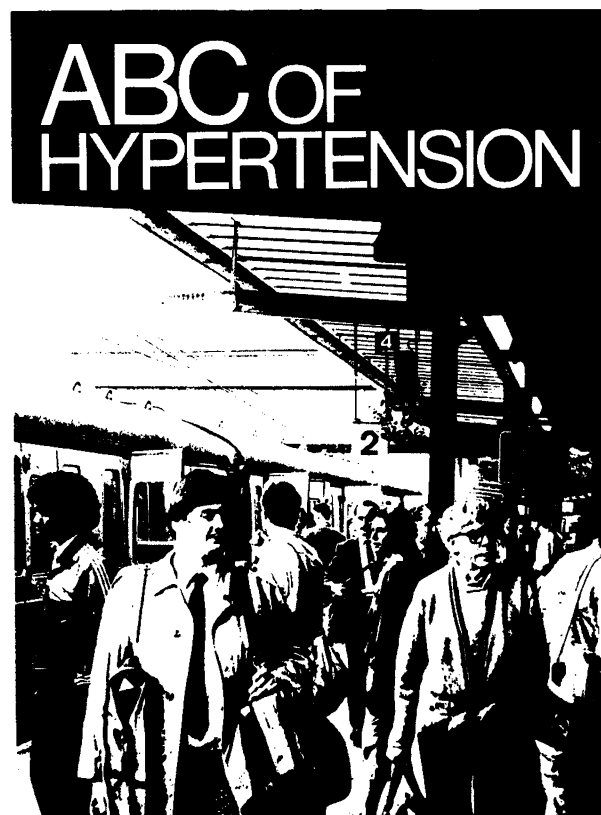
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PRESCRIBING INFORMATION:

PRESENTATION: White, convex tablets, 11mm in diameter marked SURGAM 300 on one side and  on the reverse. Each tablet contains 300mg tiaprofenic acid.

White, convex tablets, 10mm in diameter, marked SURGAM 200 on one side and  on the reverse. Each tablet contains 200mg tiaprofenic acid. Sachets containing 300mg tiaprofenic acid.

Uses/Properties: Surgam is a non-steroidal anti-inflammatory agent with marked analgesic properties.

Indications: Rheumatoid arthritis, osteoarthritis; ankylosing spondylitis; low back pain; musculo-skeletal disorders such as fibrositis, capsulitis, epicondylitis and other soft-tissue inflammatory conditions: sprains and strains, post-operative inflammation and pain, and other soft-tissue injuries.

Dosage and administration Adults: 600mg daily in divided doses. 300mg twice daily. Alternatively, 200mg three times daily.

Elderly: Current research suggests that it is not necessary to modify the dosage of Surgam in the elderly or in cases of mild to moderate renal impairment. In severe renal impairment, it is suggested that the dosage should be reduced to 200mg twice daily.

Children: There are insufficient data to recommend use of Surgam in children.

Contra-indications, warnings etc. Contra-indications: Active peptic ulceration, history of peptic ulceration, hypersensitivity to the drug. **Precautions:** Surgam should be used with care in patients with a history of severe renal or hepatic insufficiency, asthma or previous sensitivity to aspirin or other non-steroidal anti-inflammatory agents. Non-steroidal anti-inflammatory drugs may cause some sodium and fluid retention. This should be borne in mind in patients with incipient or actual congestive heart failure. Since Surgam is highly protein-bound, it may be necessary to modify the dosage of other highly protein-bound drugs, e.g. anticoagulants, sulphonamides, hypoglycaemic agents, phenytoin and certain potent diuretics when these are administered concurrently.

Pregnancy: Although animal studies have not revealed evidence of teratogenicity safety in human pregnancy and lactation cannot be assumed and, in common with other non-steroidal anti-inflammatory agents, administration during the first trimester should be avoided.

Lactation: There are no data on the passage of Surgam into the breast milk.

Side effects: Surgam is generally well tolerated. Gastro-intestinal reactions which have been reported include dyspepsia, nausea, abdominal pain, vomiting, anorexia, indigestion, heartburn, stomatitis, constipation, gastritis, flatulence or diarrhoea. In common with other non-steroidal anti-inflammatory agents, peptic ulcers, gastro-intestinal bleeding and perforation have occasionally been reported and in exceptional cases may have been associated with fatalities. Headache and drowsiness have occasionally been reported as have skin reactions, which include rash, photosensitivity, urticaria, pruritis, angio-oedema and alopecia.

Treatment of overdose: In the event of an overdose with Surgam, supportive and symptomatic therapy is indicated.

Pharmaceutical precautions Store in a cold place and protect from light.

Legal category Prescription Only Medicine.

Package quantities 300mg tablets in bottles of 60. 200mg tablets in bottles of 100. 300mg sachets in packets of 60.

Basic NHS prices and Product licence numbers Surgam 300mg £15.44 per pack of 60 0109/0109 Surgam 200mg £16.39 per pack of 100 0109/0108 Surgam 300mg sachets £15.44 per pack of 60. 0109/0127

Further information Nil. **Date of preparation** March 1987.

SURGAM

tiaprofenic acid

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