

The Official Journal of the British Society for Rheumatology

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Abbreviated Prescribing Information

Uses:

For patients who require naproxen 500mg b.d. to treat rheumatoid- or osteo-arthritis or ankylosing spondylitis and Cytotec 200mcg b.d. to prevent NSAID-induced gastroduodenal ulceration

Dosage:

One tablet of naproxen and one tablet of Cytotec twice daily with food

Contraindications:

Pregnant women, women planning a pregnancy, breast feeding women, hypersensitivity to naproxen, naproxen sodium or prostaglandins, aspirin, anti-inflammatory-induced allergy. As a prevention pack Napratec should not be used in patients with active gastroduodenal ulceration

Warnings Precautions:

Pre-menopausal women should use effective contraception and be advised of the risks of taking the products if pregnant. NSAIDs decrease platelet aggregation and prolong bleeding time.

Use with care in patients with impaired renal and hepatic function, compromised cardiac function, in those with asthma or allergic disease and in disease states where hypotension might precipitate severe complications. Caution is required if any of the following are administered concurrently: hydantoins, anti-coagulants or highly protein bound sulphonamides, diuretics, beta blockers, lithium, probenecid, methotrexate.

Naproxen adverse effects:

GI - nausea, vomiting, abdominal discomfort, bleeding, ulceration, occasionally colitis. The inclusion of Cytotec in the combination pack is to prevent naproxen-induced gastric and duodenal ulceration.

CNS - headache, insomnia, inability to concentrate and cognitive dysfunction.

Dermatological hypersensitivity - skin rashes, urticaria, angio-oedema, rarely anaphylactic reactions, eosinophilic pneumonitis, alopecia, erythema multiforme, Stevens Johnson syndrome, epidermal necrolysis, photosensitivity reactions.

Haematological - thrombocytopenia, granulocytopenia, aplastic anaemia, haemolytic anaemia. *Other* - tinnitus, hearing impairment, vertigo, mild peripheral oedema, rarely jaundice, fatal hepatitis, nephropathy, haematuria, visual disturbances, vasculitis, ulcerative stomatitis.

Cytotec adverse effects:

GI - diarrhoea, abdominal pain, dyspepsia, flatulence, nausea, vomiting.

Female reproductive - menorrhagia, vaginal bleeding, intermenstrual bleeding.

Other - skin rashes, infrequently dizziness.

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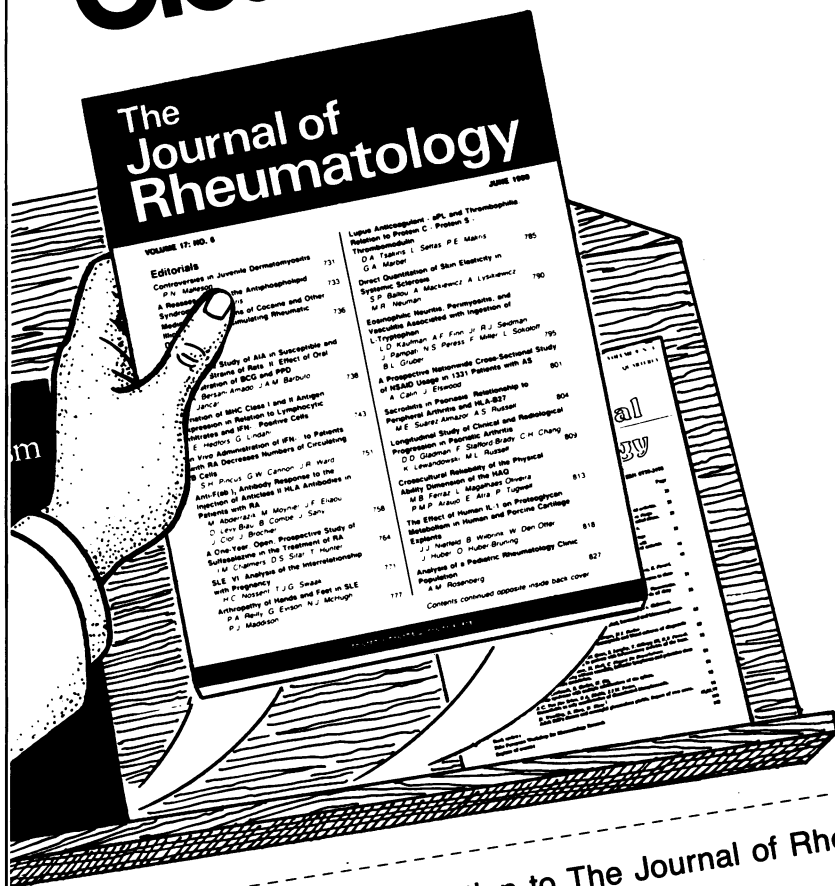
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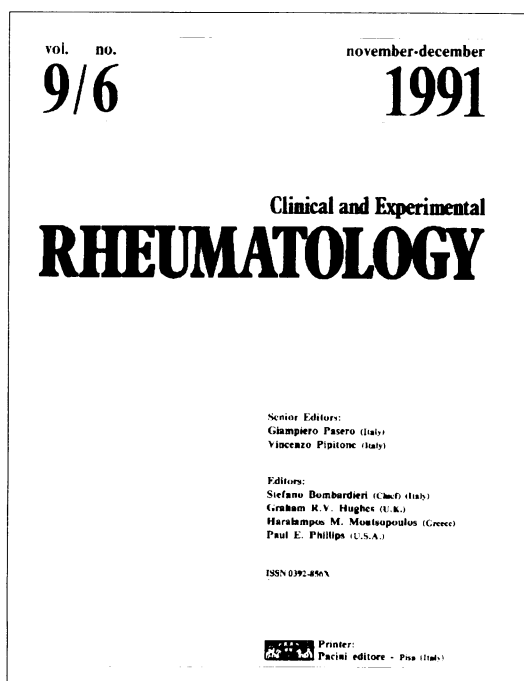
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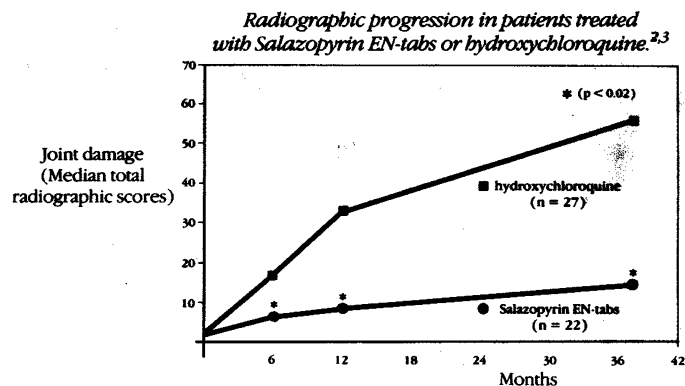
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