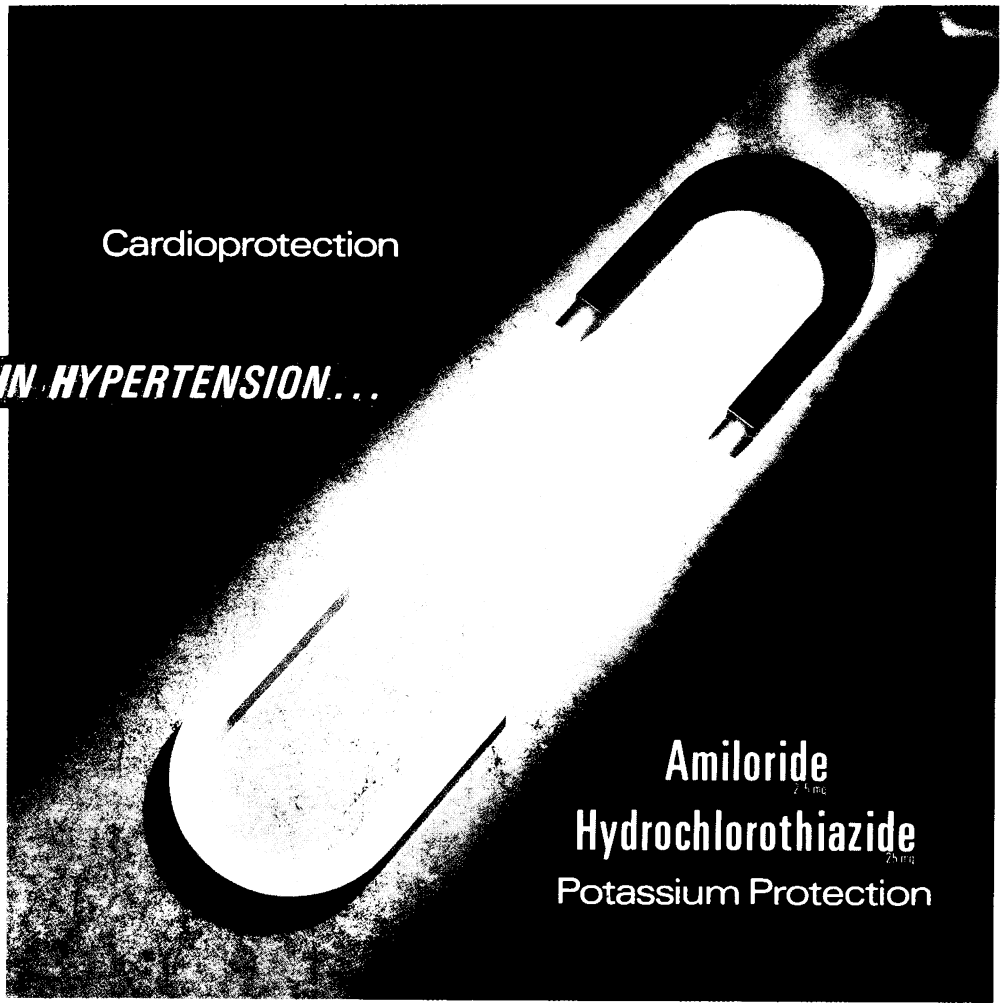
Prescribing Information
NAPROSYN Tablets (naproxen 250mg per tablet)
NAPROSYN 500 Tablets (naproxen 500mg per tablet)
NAPROSYN Suspension (naproxen 25mg/ml)
NAPROSYN Suppositories (naproxen 500mg per suppository)
Uses: Rheumatoid arthritis, osteoarthrosis, ankylosing spondylitis, acute gout and acute musculoskeletal disorders.
Dosage: For rheumatoid arthritis, osteoarthrosis and ankylosing spondylitis: 500mg to 1g daily taken in two doses at 12-hour intervals. High doses should be used with caution in the elderly. For acute gout: 750mg at once, then 250mg every eight hours until the attack has passed. For juvenile arthritis in children over 5 years: 5mg/kg body weight twice daily. For acute musculo-skeletal disorders: 500mg initially, then 250mg at 6-8 hour intervals as needed with a maximum daily dose after the first day of 1250mg.
Contra-indications: Active peptic ulceration. Hypersensitivity to naproxen or naproxen sodium formulations. Aspirin/anti-inflammatory-induced allergy.
Warnings, precautions, etc: Episodes of GI bleeding have been reported. Use with care in patients with a history of GI disease. Use with caution in patients with impaired renal or hepatic function. Monitor renal function and consider reducing dosage in patients where renal blood flow is compromised (e.g. as in extracellular volume depletion, cirrhosis of the liver, sodium restriction, congestive heart failure, pre-existing renal disease) – some elderly patients may fall in this category. Use with caution in patients with asthma or allergic disease. Caution is required if any of the following is administered concurrently: hydantoins, anti-coagulants or highly protein-bound sulphonamides; frusemide; propranolol or other beta-blockers; lithium; probenecid; methotrexate. NAPROSYN decreases platelet aggregation and prolongs bleeding time. Its use in pregnant or breast-feeding women should be avoided if possible.
Side-effects: *GI* – nausea, vomiting, pain; occasionally bleeding and ulceration. *Dermatological/hypersensitivity* – skin rashes, urticaria, angio-oedema; rarely anaphylactic reactions and eosinophilic pneumonitis. *CNS* – headache, insomnia, inability to concentrate, cognitive dysfunction. *Haematological* – thrombocytopenia, granulocytopenia, aplastic anaemia, haemolytic anaemia. *Other* – tinnitus, hearing impairment, vertigo, mild peripheral oedema (patients with compromised cardiac function may be at a greater risk on NAPROSYN): rarely jaundice, fatal hepatitis, nephropathy and ulcerative stomatitis. *Naprosyn Suppositories (local)* – rectal discomfort, soreness, burning, itching, rectal bleeding, tenesmus, proctitis.
Basic NHS Cost: Tablets 250mg £6.51 for 60 tablets, £25.98 for 250 tablets. Tablets 500mg £20.78 for 100 tablets. Suspension £7.05 for 500ml. Suppositories £2.53 for 10 suppositories.
Product Licence No.:
PL 0286/0031 – Tablets (250mg).
PL 0286/0061 – Tablets (500mg).
PL 0286/0047 – Suspension.
PL 0286/0053 – Suppositories.

SYNTEX

Further information is available from:
SYNTEX Pharmaceuticals Limited, St. Ives Road, Maidenhead, Berks. SL6 1RD.
*NAPROSYN is a trademark.

Powerful, familiar, reassuring.

Naprosyn* 500 bd.



Prescribing Notes for 'Kalten', 'Tenormin' and 'Tenormin' LS

DOSAGE

Hypertension 'Kalten' – 50 mg atenolol + 25 mg hydrochlorothiazide + 2.5 mg amiloride hydrochloride (as amiloride hydrochloride BP 2.84 mg) orally one capsule daily; recommended where monotherapy with beta-blocker or diuretic proves inadequate.
'Tenormin' – 100 mg atenolol, orally once a day.
'Tenormin' LS – 50 mg atenolol orally once a day; some patients may respond adequately to 'Tenormin' low strength (LS).
Children – 'Kalten', 'Tenormin' and 'Tenormin' LS are not recommended for use in children.
Elderly patients – Dosage requirements for 'Tenormin' and 'Tenormin' LS may be lower, especially in patients with renal impairment.
'Kalten' may be suitable for older patients.

CONTRA-INDICATIONS

'Kalten' : Heart block, hyperkalaemia, anuria, acute renal failure, severe progressive renal disease, diabetic nephropathy, blood urea over 10 mmol/l or serum creatinine over 130 micromol/l if not possible to monitor carefully and frequently. In renal impairment additional potassium conserving agents may cause hyperkalaemia.
Sensitivity to hydrochlorothiazide or amiloride hydrochloride.
'Tenormin' : Heart block.

PRECAUTIONS

Untreated cardiac failure, bradycardia, renal failure, anaesthesia, pregnancy. Disturbed fluid or electrolyte balance. Caution in patients with chronic obstructive airways disease or asthma. Atenolol modifies the tachycardia of hypoglycaemia. Co-administration with verapamil or Class I antidysrhythmic agents.
Withdrawal of clonidine.
Withdrawal of beta-blocking drugs should be gradual in patients with ischaemic heart disease.

Additional precautions for 'Kalten'

Co-administration with lithium.
Metabolic effects: Measurement of potassium levels is appropriate especially in the older patient, those receiving digitalis preparations for cardiac failure, taking abnormal (low in potassium) diet or suffering from gastrointestinal complaints.
Caution in metabolic or respiratory acidosis.
Diabetes: 'Kalten' may lower glucose tolerance. Discontinue before glucose tolerance testing.
Hyponatraemia and hypochloraemia may occur.
Hepatic or renal impairment: Caution in patients where fluid and electrolyte balance is critical.
Hyperkalaemia and hypokalaemia may occur. Discontinue treatment if increasing azotaemia and oliguria occur.
Amiloride may precipitate hepatic encephalopathy.
Jaundice may occur in cirrhotic patients.
Breast-feeding: Discontinue if 'Kalten' deemed essential.

SIDE EFFECTS

Coldness of extremities, bradycardia and muscular fatigue may occur. Sleep disturbance rarely seen. Rashes and dry eyes have been reported with beta-blockers – consider discontinuance if they occur.
With amiloride hydrochloride and hydrochlorothiazide gastrointestinal disturbances may occur. Side-effects commonly associated with diuresis, dizziness and headache, may occur.
Skin rashes and blood dyscrasias have been reported.

PRODUCT LICENCE NUMBERS AND BASIC NHS COST

'Kalten' Capsules (29/186) in calendar packs of 28, £6.70.
'Tenormin' Tablets (29/122) in calendar packs of 28, £6.98.
'Tenormin' LS Tablets (29/86) in calendar packs of 28, £4.88.

'Kalten', 'Tenormin' and 'Tenormin' LS are trade marks.

Further information is available on request from the Company.

Stuart Pharmaceuticals Limited
Stuart House, 50 Alderley Road, Wilmslow, Cheshire SK9 1RE.
STUART

New combines low strength 'Tenormin' with low dose amiloride/hydrochlorothiazide.

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