NAPROX Tablets

U.S.P. Specs.

(Naproxen Sodium USP)

Anti-inflammatory , Anti-rheumatic
Analgesic , Anti-pyretic

نیپروکس ٹیبلٹس
(نیپروکسن سوڈیم) یو ایس پی

Composition :
Each film coated tablet contains :
Naproxen Sodium USP 550 mg.
Each film coated tablet contains :
Naproxen Sodium USP 275 mg.
(Product complies USP specs.)

Naproxen sodium is an improved form of naproxen for use as an analgesic being more rapidly available and providing greater pain relief. Naproxen sodium is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations are attained 2 to 4 hours after ingestion. NAPROX (naproxen sodium) is a non-steroidal analgesic anti-inflammatory agent. It is presented as tablets containing 250mg & 500mg naproxen as sodium.

INDICATIONS:

NAPROX tablets are indicated for the relief of mild to moderate pain and treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendinitis. Bursitis, acute gout and primary dysmenorrhoea.

DOSAGE:

Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitls:
The usual dose is 500mg to 1000mg per day in two doses or as a single administration morning or evening.

Acute Gout: The recommended dose of naproxen is 750mg initially then 250mg 8 hourly till the attack has passed.

Musculoskeletal Disorders and Post-Operative Pain:
500mg twice daily and maximum 1000mg per day.

Post-Partum Pain: A single dose of 500mg is recommended.

Dysmenorrhoea: 500mg initially, then 250mg 6-8 hourly, as needed.
This represents a maximum dose of 250mg on first day and 1000mg per day thereafter.

Juvenile Rheumatoid Arthritis: Naproxen is effective at a dose of 10mg/kg/day in the treatment of juvenile rheumatoid arthritis in children over 5 years of age in two doses.
Naproxen is not recommended in any other indication in children under 16 years of age.

CONTRA-INDICATIONS:

Naproxen has been found to be well tolerated by patients. There are no known absolute contra-indications. However, naproxen may not be given in active peptic ulceration, hypersensitivity to naproxen or naproxen sodium formulations. Since the potential exists for cross-sensitivity reactions, naproxen should not be given to patients in whom aspirin or other nonsteroidal anti-inflammatory analgesic drugs induce asthma, rhinitis or urticaria.
Severe anaphylactic like reactions to naproxen have been reported in such patients.

WARNING:

Serious gastro-intestinal adverse reactions can occur at any time in patients on therapy with non-steroidal anti-inflammatory drugs. The risk of their occurrence does not seem to change with duration of therapy. Bronchospasm may be precipitated in patients suffering from, or with a history of bronchial asthma or allergic disease. Mild peripheral oedema has been observed in a few patients receiving naproxen.
Although sodium retention has not been reported in metabolic studies. It is possible that patients with questionable or compromised cardiac function may be at greater risk when taking naproxen. Each naproxen tablet contains approximately 25-50mg (about 1-2m Eq) sodium. This should be considered in patients whose overall intake of sodium must be markedly restricted.

Use in patients with impaired renal function:

As naproxen is eliminated to a large extent (95%) by urinary excretion via glomerular filtration, it should be used with great caution in patients with significantly impaired renal function and the monitoring of serum creatinine and/or creatinine clearance is advised in these patients.

Use in patients with impaired liver function:

Chronic alcoholic liver disease and probably also other forms of cirrhosis reduce the total plasma concentration of naproxen, but the plasma concentration of unbound naproxen is increased. The implication of this finding for naproxen dosing is unknown but it is prudent to use the lowest effective dose.

INTERACTION WITH OTHER DRUGS :

Due to the high plasma protein binding of naproxen, patients simultaneously receiving hydantoins, anticoagulants or a highly protein-bound sulphonamide should be observed for signs of overdosage of these drugs. No interactions have been observed in clinical studies with naproxen sodium or naproxen, anticoagulants or sulphonylureas, but caution is nevertheless advised since interaction has been seen with other non-steroidal agents of this class.

SIDE-EFFECTS :

Gastro-Intestinal: The more frequent reactions are nausea, vomiting, abdominal discomfort and epigastric distress..

Dermatological hypersensitivity: Skin rash, urticaria, angio-oedema, anaphylactic reactions to naproxen and naproxen sodium formulations, eosinophilic pneumonitis, alopecia, erythema multiforme.

Renal: Glomerular nephritis, interstitial nephritis, nephrotic syndrome, haematuria, renal papillary necrosis, renal failure.

CNS: Headache, insomnia, convulsions, inability to concentrate and cognitive dysfunction have been reported.

Haematological: Thrombocytopenia. granulocytopenia (including agranulocytosis), aplastic anaemia and haemolytic anaemia may occur rarely.

USE IN PREGNANCY AND IN BREAST FEEDING :

Teratology studies in rats and rabbits at dose levels equivalent on a human multiple basis to those which have produced fetal abnormality with certain other non-steroidal anti-inflammatory agents, e.g. aspirin; have not produced evidence of fetal damage with naproxen. As with other drugs of this type naproxen delays parturition in animals (the relevance of this finding to human patients is unknown) and also affects the human fetal cardiovascular system (closure of the dectus arteriosus). Good medical practice indicates minimal drug usage in pregnancy, and use of this class of therapeutic agents requires cautious balancing of possible, benefit against potential risk to the mother and fetus, especially in the first and third trimesters. Naproxen has been found in the milk of lactating mothers. The use of naproxen should be avoided in patients who are breast-feeding.

USE IN CHILDREN:

Naproxen is not recommended for use in children under sixteen years of age.

OVERDOSAGE:

Singnificant overdosage of the drug may be characterised by drowsiness, heart-burn, indigestion, nausea or vomiting . A few patients have experienced seizures, but it is not clear whether these were naproxen related or not. It is not known what dose of the drug would be life threatening. Should a patient ingest a large amount of naproxen accidentally or purposefully, the stomach may be emptied and usual supportive measures employed. Animal studies indicate that the prompt administration of activated charcoal in adequate amounts would tend to reduce markedly the absorption of the drug. Haemodialysis does not decrease the plasma concentration of naproxen because of its high degree of protein binding. However, haemodialysis may still be appropriate in patients with renal failure, who have taken naproxen.

AVAILABILITY:

NAPROX 275 mg film coated tablets in blisters. Pack of 2x10's.
NAPROX 550 mg film coated tablets in blisters. Pack of 2x10's.
NAPROX 550 mg film coated tablets in blisters. Pack of 3x10's.

INSTRUCTIONS: Store below 25°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children.

DOSAGE: As directed by the physician.

ہدایات: 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:
PHARMEDIC LABORATORIES (PVT) LIMITED.
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