Naprox®

Naproxen Enteric Coated Tablet / Suspension

DESCRIPTION
Naprox® is a preparation of Naproxen, a propionic acid derivative or a member of the arylacetic acid group of nonsteroidal anti-inflammatory agent (NSAIDs). It is an inhibitor of prostaglandin synthesis, which exhibits anti-inflammatory, analgesic and antipyretic activity.

INDICATIONS
Naprox® is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendonitis, bursitis and acute gout. It is also indicated for the relief of mild to moderate pain and the treatment of primary dysmenorrhoea.

DOSAGE AND ADMINISTRATION
Naprox® oral preparations should be taken with water preferably after meals.

Naprox® Enteric Coated Tablet

Adult:
For rheumatoid arthritis/ osteoarthritis/ ankylosing spondylitis:
For adults 500-1000 mg per day taken in two devided doses at 12- hour intervals. The maintenance dose is usually 500 mg per day taken in two devided doses at 12 - hour intervals.
The total daily dose of Naproxen should not exceed 1000 mg maintaining 12-hour intervals.
For acute gout:
750 mg should be given initially, then 250 mg every 8 hours until the attack has passed. Children under 16 years are not recommended.
For dysmenorrhoea:
For adults 500 mg should be given initially, followed by 250 mg at 6-8 hour intervals for upto 5 days, if necessary.
For other indications like analgesia and acute musculoskeletal disorders:
500 mg should be given initially, followed by 250 mg at 6-8 hour intervals, if necessary. Children under 16 years are not recommended.

Naprox® Suspension

Children:
For juvenile rheumatoid arthritis:
The usual dose for children over 2 years is 10 mg/kg/day given as two divided doses at 12-hour intervals. Therapy in children under 2 years of age is not recommended. The following may be used as a guide for dosage of suspension:

Child's weight	Dose
13 kg (29 lb)	2.5 mL b.i.d.
25 kg (55 lb)	5 mL b.i.d.
38 kg (84 lb)	7.5 mL b.i.d.

Or as directed by the physician

CONTRAINDICATIONS
It is contraindicated in acute peptic ulcer or if there is any hypersensitivity to Naproxen. Naproxen should not be given to patients in whom aspirin or other nonsteroidal anti-inflammatory/ analgesic drug induces asthma, rhinitis or urticaria.

USE IN PREGNANCY AND LACTATION
As with other medicines of this type, Naproxen produces delay in parturition in animals, and also affects the human foetal cardiovascular system (closure of ductus arteriosus). Therefore, naproxen should not be used during pregnancy unless clearly needed. Naproxen anion has been found in the milk of lactating mother. Because of the adverse effects of prostaglandin- inhibiting drugs on neonates, use in nursing mother should be avoided.

PRECAUTIONS
Naproxen should be given with precautions if there is any gastrointestinal diseases, bronchial asthma, allergic diseases, impaired renal function etc.

SIDE EFFECTS
The more frequent reactions are nausea, vomiting, abdominal discomfort and epigastric distress, skin rashes, urticaria, angioedema, alopecia, erythema multiforme, stevens Johnson syndrome, epidermal necrolysis, photosensitivity reactions, headache, insomnia, cognitive dysfunction, thrombocytopenia, aplastic anemia, haemolytic anemia etc. The more serious reactions like gastrointestinal bleeding, peptic ulceration, haemorrhage and perforation, colitis etc may occur occasionally.

DRUG INTERACTIONS
Naproxen and other non-steroidal anti-inflammatory drugs can reduce the anti-hypertensive effect of propranolol and other beta-blockers. The natriuretic effects of frusemide have been reported to be inhibited by some drugs of this class. Probenecid given concurrently increases Naproxen plasma levels and extends its half-life considerably. Concurrent administration of methotrexate may enhance its toxicity due to reduce tubular secretion. Animal studies indicate that the prompt administration of activated charcoal in adequate amounts would tend to reduce markedly the absorption of the drug.

OVERDOSE
Significant over dosage of the drug may be characterized by drowsiness, heartburn, indigestion, and nausea or vomiting. It is not known what doses of the drug would be life threatening.

PHARMACEUTICAL PRECAUTIONS
Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING
Naprox® 250 Tablet : Box containing 5 strips of 10 tablets each. Each enteric coated tablet contains Naproxen USP 250 mg.

Naprox® 500 Tablet : Box containing 5 strips of 10 tablets each. Each enteric coated tablet contains Naproxen USP 500 mg.

Naprox® Suspension : Bottle containing 50 mL oral suspension. Each 5 mL suspension contains Naproxen USP 125 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
BANGLADESH
® REGD. TRADEMARK
PM00848 V05