NUPRALGIN

NAPROXEN USP

Compositions:
Nupralgin 250 Tablet: Each enteric coated tablet contains Naproxen Sodium USP equivalent to Naproxen USP 250mg. Nupralgin 500 Tablet: Each enteric coated tablet contains Naproxen Sodium USP equivalent to naproxen USP 500mg.

Pharmacology:
Naproxen is a non-steroidal anti-inflammatory agent. The drug exhibits anti-inflammatory, analgesic, and antipyretic activity. Naproxen is an inhibitor of prostaglandin synthesis. Naproxen is readily and completely absorbed from G.I. tract and presence of food may delay its rate of absorption. A peak plasma concentration is attained 1 to 2 hours after ingestion. About 30% of a dose of Naproxen is metabolized in the liver. Approximately 95% of the drug is excreted in urine.

Dosage And Administration:
Adult: Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis: The usual dose is 250 mg to 500 mg daily taken at 12-hour intervals. Acute gout: 750mg initially, then 250mg every eight hours until the attack has passed. Acute musculoskeletal disorders: 500mg initially followed by 250mg at 6-8 hour intervals as needed. Dysmenorrhea: 500 mg should be given initially followed by 250 mg at 6-8 hour intervals for up to 5 days. Children: Juvenile rheumatoid arthritis: in children over five years of age at a dose of 10mg/kg day taken in two doses at 12-hour intervals.

Contraindications:
Active peptic ulceration and hypersensitivity to Naproxen. Naproxen should not be given to patients in whom aspirin or other nonsteroidal anti-inflammatory/analgesic drugs induce asthma, rhinitis or urticaria.

Warning And Precaution:
Naproxen should be given under close supervision to patients with a history of gastrointestinal disease. 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 impaired renal function and the monitoring of serum creatinine clearance is advised in these patients. Naproxen is not recommended in patients having baseline creatinine clearance less than 20 ml/minute.

Side Effects:
Gastrointestinal: The more frequent reactions are nausea, vomiting, abdominal discomfort and epigastrict distress. More serious reactions, which may occur occasionally, are gastrointestinal bleeding, peptic ulceration (sometimes with haemorrhage and perforation) and colitis. Dermatological hypersensitivity: Skin rashes, urticaria, angioedema, alopecia, photosensitivity reactions. CNS: Headache, insomnia, inability to concentrate and cognitive dysfunction have been reported.

Use in Pregnancy and Lactation:
Naproxen should be used during pregnancy only if the potential benefits justify the potential risks to the fetus. Naproxen has been found in the milk of lactating mothers. Because of the possible adverse effects of prostaglandin-inhibiting drug on neonates, use in nursing mother should be avoided.

Drug Interaction:
Naproxen can reduce the anti-hypertensive effect of propranolol and other beta-blockers. Probenecid given concurrently increases Naproxen plasma levels and extends its half-life considerably. Concurrent administration of methotrexate may enhance its toxicity due to reduced tubular secretion.

Overdosage:
Significant over dosage of the drug may be characterized by drowsiness, heartburn, indigestion, and nausea or vomiting. Animal studies indicate that the prompt administration of activated charcoal in adequate amounts would tend to reduce markedly the absorption of the drug.

Storage:
Keep in a cool (below 30°C) and dry place, protected from light. Keep out of the reach of children.

Packing:
Nupralgin 250: Each box contains 12x4 tablets in alu-alu blister pack. Nupralgin 500: Each box contains 6x4 tablets in alu-alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.