Anaflex®

Naproxen BP

Description

Anaflex® is a preparation of Naproxen. It is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties. Naproxen is a propionic acid derivative related to the acrylic acid class of drugs. It works by reducing the levels of prostaglandins, chemicals that are responsible for pain, fever and inflammation.

Indications and Uses

Anaflex® is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, juvenile rheumatoid arthritis, acute gout and acute musculoskeletal disorder (such as sprains and strains, direct trauma, lumbosacral pain, cervical spondylitis, tenosynovitis and fibrositis), migraine, post-operative pain and dysmenorrhoea.

Dosage and Administration

Adult:

Anaflex® Tablet

For rheumatoid arthritis, osteoarthritis, ankylosing spondylitis:

The usual dose of Anaflex® is 500 mg to 1 g per day taken in two divided doses at 12-hour intervals or as a single administration of Anaflex® 500 mg or Anaflex® **SR** 500 mg once daily (morning or evening) after meals.

For acute gout*:*

The initial dose of Anaflex® is 750 mg, and then 250mg every eight hours until the attack subsides.

For analgesia and acute musculoskeletal disorders:

The initial dose of Anaflex® is 500 mg, and then 250 mg at 6-8 hour intervals as needed with a maximum 1250 mg daily.

For dysmennorhoea*:*

The usual dose of Anaflex® is 500 mg should be given initially, followed by 250mg at 6-8 hour intervals for up to 5 days.

For migraine:

The usual dose of Anaflex® is 500 mg should be given initially, then 500mg at least 30 minutes after the initial dose.

Children over 5 years:

In juvenile arthritis (children over 5 years):

The usual dosage of Anaflex® is 10 mg/kg/day taken in two doses at 12-hour intervals is recommended.

Anaflex® Gel is to be applied 2-6 times a day as required and is not recommended for use in children.

Use in pregnancy & lactation

The safety of naproxen administration during pregnancy and for use in nursing mother has not been established. Therefore, the possible hazards should be weighed against the potential benefits.

Side-effects

Gastro-intestinal: Nausea, vomiting, pain, occasionally bleeding and ulceration and colitis.

Dermatological: Skin rashes, urticaria, angio-oedema; rarely anaphylactic reactions and eosinophilic pneumonitis.
Haematological: Thrombocytopenia, granulocytopenia, including agranulocytosis, aplastic anaemia.
Other: Tinnitus, hearing impairment, vertigo, mild peripheral oedema (patients with compromised cardiac function may be at a higher risk on naproxen), rarely jaundice, fatal hepatitis, nephropathy, haematuria, visual disturbances, vasuculitis, aseptic meningitis and ulcerative stomatitis.

Contraindications
Naproxen is contraindicated in patients' active peptic ulceration, hypersensitivity to naproxen or naproxen sodium formulations, aspirin/other NSAIDs.

Precautions
Naproxen should be used with care in patients with a history of GI disease, asthma, or allergic disease, impaired renal and hepatic function. Naproxen decreases platelet aggregation and prolongs bleeding time.

Overdosage
Overdosage with naproxen may be characterized by drowsiness, heartburn, indigestion, nausea and vomiting. No evidences of toxicity or late sequelae have been reported 5-15 months after ingestion, for three to seven days, of doses up to 3g/day.

Drug interactions
Caution is required if any of the following is administered concurrently with naproxen: hydantoins, anticoagulants or highly protein-bound sulphonamides, furesamide, propranolol or other beta-blockers, lithium, probenecid, methotrexate.

Pharmaceutical precautions

Protect from light, store bellow 30°C and keep away from children.

Presentation
Anaflex® 250 mg Tablets: White, round, biconvex enteric coated tablet; each tablet contains 250 mg Naproxen BP.
Anaflex® 500 mg Tablets: White, sleek, oblong, enteric coated tablet; each tablet contains 500 mg Naproxen BP.
Anaflex® SR 500 mg tablet: White, oval, sustained release tablet; each tablet contains Naproxen BP 500 mg
Anaflex® Gel: A transparent, pleasant-smelling, homogeneous gel containing Naproxen BP 10% w/w.

Package Quantities
Anaflex® 250 mg tablet: Carton of 50 tablets in Alu-PVC blister.
Anaflex® 500 mg tablet: Carton of 30 tablets in Alu-PVC blister.
Anaflex® SR 500 mg tablet: Carton of 20 tablets in Alu-PVC blister.
Anaflex® Gel: Tubes of 15 gm & 30 gm.

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