

# Anaflex<sup>®</sup>

## Naproxen

### Composition

**Anaflex<sup>®</sup> 250 mg Tablet:** Each enteric coated tablet contains Naproxen BP 250 mg.

**Anaflex<sup>®</sup> 500 mg Tablet:** Each enteric coated tablet contains Naproxen BP 500 mg.

**Anaflex<sup>®</sup> SR 500 mg Tablet:** Each tablet contains Naproxen BP 500 mg.

**Anaflex<sup>®</sup> Suspension:** Each 5 ml contains Naproxen BP 125 mg.

**Anaflex<sup>®</sup> Gel:** Each gram gel contains Naproxen BP 100 mg (Naproxen BP 10% w/w).

### Pharmacology

**Anaflex<sup>®</sup>** is a preparation of Naproxen which 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.

### Indication

**Anaflex<sup>®</sup>** 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 dysmenorrhea.

### Dose and administration

#### **Adults**

#### **Anaflex<sup>®</sup> Tablet**

**For rheumatoid arthritis, osteoarthritis, ankylosing spondylitis:** The usual dose of **Anaflex<sup>®</sup>** is 500 mg to 1 g per day taken in two divided doses at 12 hour intervals or as a single administration of **Anaflex<sup>®</sup> 500 mg** or **Anaflex<sup>®</sup> SR 500 mg** once daily (morning or evening) after meals.

**For acute gout:** The initial dose of **Anaflex<sup>®</sup>** is 750 mg, and then 250 mg every eight hours until the attack subsides.

**For analgesia and acute musculoskeletal disorders:** The initial dose of **Anaflex<sup>®</sup>** is 500 mg and then 250 mg at 6-8 hour intervals as needed with a maximum 1250 mg daily.

**For dysmenorrhea:** The usual dose of **Anaflex<sup>®</sup>** is 500 mg should be given initially, followed by 250 mg at 6-8 hour intervals for up to 5 days.

**For migraine:** The usual dose of **Anaflex<sup>®</sup>** is 500 mg should be given initially, then 500 mg at least 30 minutes after the initial dose.

#### **Children over 5 years**

**In juvenile rheumatoid arthritis (children over 5 years):** The usual dosage of **Anaflex<sup>®</sup>** is 10 mg/kg/day taken in two doses at 12 hour intervals is recommended.

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

## Contraindication

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

## Warning and precaution

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.

## Side effects

The most common side effects of naproxen are nausea, vomiting, pain, occasionally bleeding, ulceration, colitis, skin rashes, urticaria, angio-oedema; eosinophilic pneumonitis, thrombocytopenia, granulocytopenia, including agranulocytosis, aplastic anaemia, tinnitus, hearing impairment, vertigo, mild peripheral oedema (patients with compromised cardiac function may be at a higher risk on naproxen), fatal hepatitis, nephropathy, haematuria, visual disturbances, vasculitis, aseptic meningitis and ulcerative stomatitis.

## Use in pregnancy and 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.

## Drug interaction

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 and methotrexate.

## Overdose

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

## Storage

Store in a cool (below 30°C) and dry place protected from light. Keep away from the reach of children.

## Packing

**Anaflex<sup>®</sup>** 250 mg Tablet: Carton of 50 tablets in blister pack.

**Anaflex<sup>®</sup>** 500 mg Tablet: Carton of 30 tablets in blister pack.

**Anaflex<sup>®</sup> SR** 500 mg Tablet: Carton of 20 tablets in blister pack.

**Anaflex<sup>®</sup>** Suspension: Bottle of 50 ml.

**Anaflex<sup>®</sup>** Gel: Tubes of 15 g and 30 g.

® Registered Trade Mark



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