ANAF TABLETS 100 mg

(Flurbiprofen 100 mg)
NON-STEROIDAL
ANTI-INFLAMMATORY DRUG

DESCRIPTION

Anaf Tablets contain flurbiprofen, a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid derivative group. Flurbiprofen has analgesic, anti-inflammatory and antipyretic activity.

COMPOSITION

Each tablet contains: **Flurbiprofen 100 mg**. Excipients: as per approved product formula. For oral administration.

CLINICAL PHARMACOLOGY

Flurbiprofen inhibits cyclo-oxygenase (COX) activity and reduces prostaglandin synthesis, thereby relieving inflammation and pain. Following oral administration, it is absorbed from the gastrointestinal tract and is extensively protein bound. It is metabolized mainly in the liver and its metabolites are excreted primarily in urine.

INDICATIONS

For symptomatic relief in rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, musculoskeletal disorders, tendinitis, bursitis, low back pain, sprains and strains. It may also be prescribed for mild to moderate pain such as dental pain, postoperative pain and primary dysmenorrhoea, according to approved local indications.

DOSAGE AND ADMINISTRATION

For oral use, preferably with or after food. Use the **lowest effective dose for the shortest duration** necessary to control symptoms. Dosage must be individualized by the physician.

Adults: Generally 150-200 mg daily in divided doses, using suitable tablet strengths. In severe symptoms or acute exacerbations, the prescriber may increase the total to a maximum of **300 mg daily** in divided doses. Do not exceed **100 mg as a single dose** in a multiple-dose regimen.

Dysmenorrhoea: 100 mg at onset, then 50-100 mg at 4-6 hour intervals if prescribed, without exceeding 300 mg in 24 hours.

Children: Not recommended below 12 years. **Elderly:** Use the lowest effective dose with close monitoring for gastrointestinal, renal and cardiovascular adverse effects.

CONTRAINDICATIONS

Hypersensitivity to flurbiprofen or ingredients; previous asthma, urticaria or allergic reactions after aspirin or other NSAIDs; active or recurrent peptic ulceration, gastrointestinal bleeding or perforation; severe heart, kidney or liver failure; history of NSAID-associated GI bleeding/perforation; use during coronary artery bypass graft (CABG) surgery; third trimester of pregnancy. Confirm all contraindications against locally approved labeling.

SPECIAL WARNINGS AND PRECAUTIONS

Cardiovascular: NSAIDs may increase the risk of myocardial infarction, stroke and other serious thrombotic events, including events occurring early in treatment. Risk can increase with treatment duration. Use cautiously in patients with hypertension, heart disease or cardiovascular risk factors.

Gastrointestinal: Serious bleeding, ulceration or perforation may occur at any time, sometimes without warning. Risk is greater in older patients and those with previous ulcers or GI bleeding, and with concurrent anticoagulants, corticosteroids, antiplatelets or certain antidepressants. Stop treatment and seek urgent assessment for black stools, vomiting blood or severe abdominal pain.

Renal and hepatic: NSAIDs may impair kidney function, particularly in dehydration, older age, heart failure or concurrent diuretics/ACE inhibitors. Monitor renal function and liver tests when appropriate. Discontinue if signs of significant liver injury appear.

Other: May cause fluid retention, edema, elevated blood pressure, bronchospasm, anaphylaxis or severe skin reactions including Stevens-Johnson syndrome. Discontinue at first evidence of rash, mucosal lesions, breathing difficulty or serious allergic reaction.

Use caution in patients with asthma, bleeding disorders, systemic lupus erythematosus, inflammatory bowel disease or previous drug-induced ulcers. Flurbiprofen may mask symptoms of infection. Long-term treatment requires clinical monitoring.

DRUG INTERACTIONS

Avoid concomitant use with other NSAIDs (including selective COX-2 inhibitors) and high-dose aspirin. Increased bleeding risk occurs with warfarin and other anticoagulants, antiplatelet drugs, oral corticosteroids and SSRIs. Diuretics, ACE inhibitors and ARBs may have reduced effects and increase renal risk. NSAIDs can increase lithium or methotrexate toxicity; caution is also required with ciclosporin, tacrolimus and certain other medicines. Review all concurrent medicines before prescribing.

PREGNANCY

NSAID use from about 20 weeks of pregnancy may cause fetal renal dysfunction and low amniotic fluid. Avoid use from 20 weeks unless specifically advised by a physician and avoid use during the third trimester because of fetal cardiopulmonary and renal risks and possible effects on labor. Women planning pregnancy should consult their physician; NSAIDs can temporarily impair fertility.

LACTATION

Small amounts of flurbiprofen may pass into breast milk. Use during breastfeeding only on professional advice after assessing benefits and risks.

PEDIATRIC AND GERIATRIC USE

Not recommended in children younger than 12 years. Older patients have greater susceptibility to serious GI events and renal impairment; use carefully with close monitoring.

ADVERSE REACTIONS

Gastrointestinal: Dyspepsia, abdominal pain, nausea, vomiting, diarrhoea, constipation, flatulence, ulceration and gastrointestinal bleeding or perforation.

Nervous system: Headache, dizziness, drowsiness, fatigue and occasionally visual disturbances.

Skin and hypersensitivity: Rash, itching, urticaria, photosensitivity and rarely severe bullous skin reactions or anaphylaxis.

Renal and cardiovascular: Edema, hypertension, fluid retention, renal impairment and increased risk of serious thrombotic events.

Other: Changes in liver enzymes, hepatitis, hematological abnormalities and bronchospasm may occur. Report unexpected or serious adverse reactions promptly.

OVERDOSAGE

Symptoms may include nausea, vomiting, abdominal pain, drowsiness, dizziness, gastrointestinal bleeding, renal impairment, seizures or coma. No specific antidote is available. Obtain urgent medical attention. Treatment is symptomatic and supportive; activated charcoal may be considered soon after a substantial ingestion by qualified medical staff.

EFFECTS ON DRIVING AND MACHINERY

Dizziness, somnolence and visual disturbances may impair driving or machine operation. Avoid these activities if affected.

STORAGE CONDITIONS

Store below 25°C, protected from heat and moisture, unless the approved Anaf stability data specify otherwise. Keep out of the reach of children.

PRESENTATION

Anaf Tablets 100 mg: 3 x 10 tablets (30 tablets) in blister packs.

Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore - Pakistan.

Prescription medicine. Draft for QA / regulatory approval before printing.