

Fritt

Naproxen USP

Composition

Fritt 250 tablet : Each enteric coated tablet contains Naproxen Sodium USP equivalent to Naproxen 250 mg.

Fritt 500 tablet : Each enteric coated tablet contains Naproxen Sodium USP equivalent to Naproxen 500 mg.

Pharmacology

Fritt (Naproxen Sodium) is a Non-Steroidal Anti-inflammatory drug. The drug exhibits anti-inflammatory, analgesic, and antipyretic activities by inhibiting prostaglandin synthesis. Both Naproxen and Naproxen Sodium are completely absorbed from the GIT but the peak plasma concentration is attained about 1-2 hours after ingestion of Naproxen Sodium whereas that takes 2-4 hours after ingestion of Naproxen.

Indication

Fritt is indicated for the relief of symptoms of rheumatoid arthritis, both of acute flares and long term management of the disease. It is also used in the treatment of osteoarthritis (degenerative arthritis), ankylosing spondylitis, juvenile rheumatoid arthritis, tendinitis, bursitis, acute gout, acute musculoskeletal disorders (such as sprains, direct trauma and fibrositis), migraine and dysmenorrhoea.

Dosage & Administration

Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis: 250 to 500 mg twice daily. May be increased to 1.50 gm for limited periods. Morning and evening doses do not have to be equal and use of the drug more frequently than twice daily is not necessary. Symptomatic arthritis improvement usually begins in 2 weeks, if no improvement is seen, consider a trial for 2 more weeks.

Mild to moderate pain, primary dysmenorrhoea, acute tendinitis, bursitis and dysmenorrhoea: 500 mg initially, followed by 250 mg every 6 to 8 hours as required. Do not exceed 1.375 gm total daily dose. *Acute gout:* 750 mg, then 250 mg every 8 hours until attack subsides. *Juvenile arthritis (children over 5 years):* 10 mg/kg daily in two divided doses is recommended.

Precaution & Contraindication

Naproxen should be used with caution in patients with cardiac, hepatic and renal impairment, coagulation defect and previous history of gastro-intestinal ulceration. The drug is contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAIDs - which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAIDs.

Side Effect

Gastro-intestinal discomfort: nausea, diarrhoea and occasionally bleeding and ulceration.

Hypersensitivity reactions: notably with bronchospasm, rashes and angioedema. CNS side effect: drowsiness, headache, fluid retention, vertigo, hearing disturbances such as tinnitus and photosensitivity.

Drug Interaction

Use in patients receiving ACE inhibitors may potentiate renal diseases. Drug which are Albumin-bound may be displaced from their binding sites as a result of the naproxen anions' affinity for protein. Use with caution when given concomitantly with coumarin-type anticoagulants, sulfonyleureas. Concomitant administration is not recommended because reduction in the antihypertensive effect of propranolol and other beta-blockers may occur. Concurrent administration of probenecid or methotrexate should be done cautiously to prevent potential naproxen and methotrexate toxicity respectively.

Use in Pregnancy & lactation

There are no well controlled studies in pregnant women. The drug should not be used during pregnancy unless clearly needed. Because of the possible adverse effects of prostaglandin inhibiting drugs on neonates, use in nursing mothers must be avoided.

Storage

Store in a cool and dry place and protect from light. Keep out of the reach of children.

How Supplied

Fritt 250 tablet : Box containing 5 x 10's tablet in blister pack.

Fritt 500 tablet : Box containing 5 x 10's tablet in blister pack.



Manufactured by
SOMATEC PHARMACEUTICALS LTD.
Sarulia, Demra, Dhaka, Bangladesh