

Composition:

Etoflam™ 60 Tablet: Each film-coated tablet contains Etoricoxib INN 60 mg.

Etoflam™ 90 Tablet: Each film-coated tablet contains Etoricoxib INN 90 mg.

Etoflam™ 120 Tablet: Each film-coated tablet contains Etoricoxib INN 120 mg.

Pharmacology:

Etoflam™ (Etoricoxib) is a Non-Steroidal Anti-Inflammatory Drug (NSAID) that exhibits anti-inflammatory, analgesic and antipyretic activities. It is a potent, orally active, highly selective cyclooxygenase-2 (COX-2) inhibitor within and above the clinical dose range. COX-2 has been shown to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation and fever. Selective inhibition of COX-2 by Etoricoxib decreases these clinical signs and symptoms with decreased GI toxicity and without effects on platelet function.

Indications:

Etoricoxib is indicated for relief of pain and inflammation in-osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, chronic low back pain, other chronic musculoskeletal disorders, acute gout, dysmenorrhoea & following dental surgery.

Dosage & administration:

Adult and adolescent over 16 years-**Osteoarthritis, chronic musculoskeletal disorders & dysmenorrhoea:** 60 mg, once daily. **Rheumatoid arthritis:** 90 mg, once daily. **Pain following dental surgery & acute gout:** 120 mg, once daily.

OR AS DIRECTED BY THE PHYSICIAN.

Contra-indications:

It is contraindicated in patients with hypersensitivity to any component of this product, patients with inflammatory bowel disease, severe congestive heart failure.

Warning & precautions:

In patients with renal disease, treatment with it is not recommended. Clinical experience in patients with estimated creatinine clearance of <30 ml/min is very limited. If therapy with it must be initiated in such patients, close monitoring of the patient's renal function is advisable. Caution should be used when initiating treatment with it in patients with considerable dehydration. It is advisable to rehydrate patients prior to starting therapy with it. The possibility of fluid retention, oedema or hypertension should

be taken into consideration when it is used in patients with pre-existing oedema, hypertension, or heart failure. Independent of treatment, patients with a prior history of GI perforation, ulcers and bleeding (PUB) and patients greater than 65 years of age are known to be at a higher risk for a PUB. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver function test has occurred, should be evaluated for persistently abnormal liver function tests. If persistently abnormal liver function tests (three times the upper limit of normal) are detected, it should be discontinued. It should be used with caution in patients who have previously experienced acute asthmatic attacks, urticaria or rhinitis, which were precipitated by salicylates or non-selective cyclooxygenase inhibitors. It may mask fever, which is a sign of infection.

Side effects:

Dry mouth, taste disturbance, mouth ulcers, flatulence, constipation, appetite and weight changes, chest pain, fatigue, paraesthesia, influenza-like syndrome & myalgia.

Use in pregnancy & lactation:

Pregnancy: Etoricoxib should not be used in pregnancy. It may be used during the first two trimesters of pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether this drug is excreted in human milk.

Drug interaction:

Oral anticoagulants, diuretics and ACE inhibitors, Acetylsalicylic acid, Cyclosporin and Tacrolimus, Lithium, Methotrexate, oral contraceptives, Prednisone/Prednisolone, Digoxin, drugs metabolized by sulfo-transferases (Ethinyl Estradiol), drugs metabolized by CYP isoenzymes, Ketoconazole, Rifampicin, and Antacids have interaction with Etoricoxib.

Storage:

Store in a cool and dry place below 30°C, protect from light. Keep out of the reach of children.

Packing:

Etoflam™ 60 Tablet: Each box contains 30 tablets in blister packs.

Etoflam™ 90 Tablet: Each box contains 30 tablets in blister packs.

Etoflam™ 120 Tablet: Each box contains 20 tablets in blister packs.

Manufactured by:

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.