

E-coxib

Etoricoxib INN 60mg , 90mg & 120mg Tablet

Composition : **E-coxib-60** : Each film coated tablet contains Etoricoxib INN 60mg.

E-coxib-90 : Each film coated tablet contains Etoricoxib INN 90mg.

E-coxib-120 : Each film coated tablet contains Etoricoxib INN 120mg.

Pharmacology : Etoricoxib is a selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range.

Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Etoricoxib is approximately 92% bound to human plasma protein. Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion.

Indications : Etoricoxib helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout. Etoricoxib is also used for the short term treatment of moderate pain after dental surgery in people 16 years of age and older.

Dosage and administration : **Adult and adolescent over 16 years :** **Osteoarthritis:** The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed. **Rheumatoid arthritis:** The recommended dose is 60 mg etoricoxib once a day. The dose can be increased to a maximum of 90 mg. **Ankylosing spondylitis:** The recommended dose is 60 mg etoricoxib once a day. The dose can be increased to a maximum of 90 mg once a day if needed. **Acute pain conditions :** Etoricoxib should be used only for the acute painful period. **Gout:** The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment. **Postoperative dental surgery pain:** The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment. Or, as directed by the registered physician.

Contraindications: It is contraindicated in patients with known hypersensitivity to Etoricoxib or any other component of this formulation, patients with active peptic ulceration or active gastrointestinal (GI) bleeding, Patients who have developed sign and symptoms of bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria, or allergic type reactions after taking acetylsalicylic or NSAIDs including COX-2 (cyclooxygenase-2) inhibitors, patients having severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥10), estimated renal creatinine clearance <30 ml/min, congestive heart failure (NYHA II-IV), inflammatory bowel disease, established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

Precautions: In patient with advanced renal disease, treatment with Etoricoxib is not recommended. Clinical experience in patients with estimated creatinine clearance of <30ml/min is very limited. 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 (three times the upper limit of normal) are detected, it should be discontinued. Caution should be used when initiating treatment with it in patients with considerable dehydration, oedema, hypertension or heart failure, 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 high risk for a PUB, who have previously experienced acute asthmatic attacks, urticaria or rhinitis, which were precipitated by salicylates or non-selective cyclooxygenase using it in patients being treated for infection. It may mask fever, which is a sign of infection. The physician should be aware of this when using it in patients being treated for infection.

Side effects : Most common adverse reactions include : Dry mouth, taste disturbance, mouth ulcers, flatulence, constipation, appetite and weight changes, chest pain, fatigue, paraesthesia, influenza-like syndrome and myalgia.

Use in pregnancy and lactation : Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, etoricoxib must be discontinued. The use of etoricoxib, as with any drug substance known to inhibit COX2, is not recommended in women attempting to conceive. It is not known whether etoricoxib is excreted in human milk. Women who use etoricoxib must not breast feed.

Use in Child : Etoricoxib is contraindicated to children and adolescents under 16 years of age.

Drug interactions : Etoricoxib may interact with the following: oral anticoagulants, diuretics, ACE inhibitors, acetylsalicylic acid, cyclosporin and tacrolimus, lithium, methotrexate, oral contraceptives, prednisone/ prednisolon, digoxin, drugs metabolized by sulfotransferases (ethinyl estradiol), drugs metabolized by CYP isoenzymes, ketoconazole, rifampicin and antacids.

Overdose : In the event of overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the GI tract, employ clinical monitoring and institute supportive therapy, if required.

Storage : Store below 30°C in a dry place. Keep out of the reach of children.

Packing : **E-coxib-60** : Each box contains 28's tablet in a blister pack.

E-coxib-90 : Each box contains 28's tablet in a blister pack.

E-coxib-120 : Each box contains 30's tablet in a blister pack.



Manufactured by

DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh

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