Etorix®

Etoricoxib film coated tablet

DESCRIPTION

Etorix® is the preparation of Etoricoxib. It is a nonsteroidal anti- inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic and antipyretic activities in animal models. 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

Pain and inflammation in osteoarthritis, in rheumatoid arthritis and in other chronic musculoskeletal disorders, acute gout, pain of dysmenorrhoea and pain following dental surgery.

DOSAGE AND ADMINISTRATION

Adult and adolescent over 16 years:

- In case of osteoarthritis, dysmenorrhoea, chronic musculoskeletal disorders: 60 mg once daily
- In case of rheumatoid arthritis: 90 mg once daily
- In case of pain following dental surgery & acute gout: 120 mg once daily

Safety and effectiveness of Etoricoxib in paediatric patients have not been established.

CONTRAINDICATIONS

It is contra-indicated in inflammatory bowel disease, severe congestive heart failure.

USE IN PREGNANCY AND LACTATION

As with other drugs known to inhibit prostaglandin synthesis, use of it should be avoided in late pregnancy because it may cause premature closure of the ductus arteriosus. It should be used during the first two trimesters of pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether this drug is excreted in human milk.

SIDE-EFFECTS

Side-effects of Etoricoxib are dry mouth, taste disturbance, mouth ulcers, flatulence, constipation, appetite and weight changes, chest pain, fatigue, paraesthesia, influenza-like syndrome, myalgia.

PRECAUTIONS

In patients with advanced 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. The physician should be aware of this when using it in patients being treated for infection.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Etorix® 60 tablet : Box containing 5 strips of 10 tablets each. Each film coated tablet contains Etoricoxib INN 60 mg.

Etorix® 90 tablet : Box containing 4 strips of 10 tablets each. Each film coated tablet contains Etoricoxib INN 90 mg.

Etorix® 120 tablet : Box containing 3 strips of 10 tablets each. Each film coated tablet contains Etoricoxib INN 120 mg.

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