Temcox®

Etoricoxib

COMPOSITION:

Temcox ® 60 Tablet : Each film coated tablet contains Etoricoxib INN 60 mg.
Temcox ® 90 Tablet : Each film coated tablet contains Etoricoxib INN 90 mg.
Temcox ® 120 Tablet : Each film coated tablet contains Etoricoxib INN 120 mg.

PHARMACOLOGY:

Temcox ® (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.

INDICATION:

Temcox ® (Etoricoxib) is indicated for relief of pain and inflammation in-

- Osteoarthritis,
- Rheumatoid Arthritis,
- Ankylosing spondylitis,
- Other Chronic Musculoskeletal Disorders,
- Acute Gout,
- Dysmenorrhoea &
- Following Dental Surgery.

DOSE & 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.

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

CONTRA-INDICATION:

Etoricoxib is contraindicated to patients with known hypersensitivity to Etoricoxib, patients with active peptic ulceration or gastro-intestinal (GI) bleeding, patients who have developed signs of asthma, acute rhinitis, nasal polyps, angioneurotic oedema or urticaria following the administration of acetylsalicylic acid or other Non-Steroidal Anti-inflammatory Drugs (NSAIDs), patient having inflammatory bowel disease, severe congestive heart failure.

WARNING AND PRECAUTION:

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.

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:

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.

USE IN CHILDREN & ADOLESCENTS:

Do not give this medicine to children and adolescents under 16 years of age.

DRUG INTERACTION:

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

OVERDOSE:

There have been reports of acute overdosage with etoricoxib, although adverse experiences were not reported in the majority of cases. The most frequently observed adverse experiences were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, cardiorenal events).

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Temcox ® 60 Tablet : Each box containing 3x10's tablet in blister pack.
Temcox ® 90 Tablet : Each box containing 3x10's tablet in blister pack.
Temcox ® 120 Tablet : Each box containing 2x10's tablet in blister pack.

Manufactured by
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