

COMPOSITION

Tory[®] 60 Tablet: Each film-coated tablet contains Etoricoxib INN 60 mg. Tory[®] 90 Tablet: Each film-coated tablet contains Etoricoxib INN 90 mg. Tory[®] 120 Tablet: Each film-coated tablet contains Etoricoxib INN 120 mg.

PHARMACOLOGY

Tory ® (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

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

- osteoarthritis,
- rheumatoid arthritis,
- · other chronic musculoskeletal disorders,
- acute gout,
- dysmenorrhoea, &
- following dental surgery.

DOSAGE AND 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.

CONTRAINDICATION & PRECAUTION

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, to children and adolescents under 16 years of age.

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 EFFECT

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

DRUG INTERACTION

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

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.

STORAGE

Store at a cool & dry place protected from light & moisture. Keep out of reach of children.

HOW SUPPLIED

Tory ® 60 Tablet : Box containing 6 x 5 tablets in blister pack.

Tory ® 90 Tablet : Box containing 6 x 5 tablets in blister pack.

Tory ® 120 Tablet : Box containing 4 x 5 tablets in blister pack.

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Manufactured by



Square Pharmaceuticals Ltd. Bangladesh