Rito®

Etoricoxib INN

Description
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.

Mode of action
Etoricoxib exhibits anti-inflammatory, analgesic and antipyretic activities by inhibiting cyclooxygenase-2 (COX-2) enzyme and decreases these clinical signs and symptoms with decreased GI toxicity and without effects on platelet function.

Pharmacokinetics
Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Dosing with food has no effect on the extent of absorption of etoricoxib after administration of a 120 mg dose. The rate of absorption is affected, resulting in a 36% decrease in Cmax and an increase in Tmax by 2 hours. Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 μg/ml. Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion.

Composition
Rito® 60 Tablet: Each film-coated tablet contains Etoricoxib INN 60 mg.
Rito® 90 Tablet: Each film-coated tablet contains Etoricoxib INN 90 mg.
Rito® 120 Tablet: Each film-coated tablet contains Etoricoxib INN 120 mg.

Indications
Rito® (Etoricoxib) is indicated for relief of pain and inflammation in
- Osteoarthritis,
- Rheumatoid arthritis,
- 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. Safety and effectiveness of Etoricoxib in pediatric patients have not been established.

Contraindication
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.

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 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.

Precautions
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.

Drug interactions
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.

Storage
Store in a cool and dry place, protected from light.

Packaging
Rito® 60 Tablet: Each box containing 10X3 tablets in blister pack.
Rito® 90 Tablet: Each box 10X3 tablets in blister pack.
Rito® 120 Tablet: Each box 10X2 tablets in blister pack.

Opsonin Pharma
Ideas for healthcare

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