Ribox®

Etoricoxib

Tablet

Description

Etoricoxib is a COX-2 selective inhibitor which is 106.0 times more selective for COX-2 inhibition over COX-1.

Indication

For the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.

Dosage and Administration

Osteoarthritis: The recommended dose is 30 mg once daily. In some patients with insufficient relief from symptoms, an increased dose of 60 mg once daily may increase efficacy. In the absence of an increase in therapeutic benefit, other therapeutic options should be considered.

Rheumatoid arthritis: The recommended dose is 90 mg once daily.

Acute gouty arthritis: The recommended dose is 120 mg once daily. Etoricoxib 120 mg should be used only for the acute symptomatic period. In clinical trials for acute gouty arthritis, Etoricoxib was given for 8 days.

Ankylosing spondylitis: The recommended dose is 90 mg once daily.

Elderly: No dosage adjustment is necessary for elderly patients. As with other drugs, caution should be exercised in elderly patients.

Paediatric patients: Etoricoxib is contra-indicated in children and adolescents under 16 years of age.

Pregnancy and Lactation

The use of Etoricoxib, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive. As Etoricoxib is excreted in the milk of lactating rats so women who use Etoricoxib must not breast feed.

Contraindication

Etoricoxib is contraindicated to

- Hypersensitivity to the active substance or to any of the excipients.
- Active peptic ulceration or active gastro-intestinal (GI) bleeding.
- Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria, or allergic-type reactions after taking acetylsalicylic acid or NSAIDs including COX-2 (cyclooxygenase-2) inhibitors.
- Pregnancy and lactation.
- Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score 10).
- Estimated renal creatinine clearance <30 ml/min.
- Children and adolescents under 16 years of age.
- Inflammatory bowel disease.
- Congestive heart failure (NYHA II-IV).
- Patients with hypertension whose blood pressure is persistently elevated above 140/90mmHg and has not been adequately controlled.
- Established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease.

Adverse Reaction

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

Precautions

Upper gastrointestinal complications like perforations, ulcers or bleedings (PUBs) occurred in patients treated with Etoricoxib. COX-2 inhibitor may be associated with a risk of thrombotic events (especially myocardial infarction and stroke), relative to placebo and some NSAIDs. Under conditions of compromised renal perfusion, administration of Etoricoxib may cause a reduction in prostaglandin formation and, secondarily, in renal blood flow, and thereby impair renal function. As with other medicinal products known to inhibit prostaglandin synthesis, fluid retention, oedema and hypertension have been observed in patients taking Etoricoxib. Elevations of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) have been reported in approximately 1% of patients in clinical trials treated for up to one year with Etoricoxib 30, 60 and 90 mg daily. Skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs and some selective COX-2 inhibitors during post-marketing.

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.

Overdosage

Administration of single doses of Etoricoxib up to 500 mg and multiple doses up to 150 mg/day for 21 days did not result in significant toxicity. 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.

Pharmaceutical Precaution

Store in cool & dry place, away from children.

Commercial Pack

Ribox® 60 tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Etoricoxib INN 60 mg.

Ribox® 90 tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Etoricoxib INN 90 mg.

Ribox® 120 tablet: Box containing 20 tablets in 2 x 10's blister strips. Each tablet contains Etoricoxib INN 120 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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