

ETOXIB

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **ETOXIB** [Etoricoxib Tablets I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Etoricoxib is an oral, selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range. Across clinical pharmacology studies, ETOXIB produced dose-dependent inhibition of COX-2 without inhibition of COX-1 at doses up to 150 mg daily. Etoricoxib did not inhibit gastric prostaglandin synthesis and had no effect on platelet function.

INDICATION: It is used as a non-steroidal anti-inflammatory drug (NSAID) for symptomatic relief of osteoarthritis, rheumatoid arthritis, gouty arthritis. Acute pain associated with dental surgery, primary dysmenorrhoea.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. • Active peptic ulceration or active gastro-intestinal (GI) bleeding. • Patients who, after taking acetylsalicylic acid or NSAIDs including COX-2 (cyclooxygenase-2) inhibitors, experience bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria, or allergic-type reactions. • Pregnancy and lactation. • Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score \geq 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 140/90 mmHg and has not been adequately controlled. • Established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease.

WARNINGS & PRECAUTIONS: *Gastrointestinal effects:* Upper gastrointestinal complications [perforations, ulcers or bleedings (PUBs)], some of them resulting in fatal outcome, have occurred in patients treated with etoricoxib. *Cardiovascular effects:* Clinical trials suggest that the selective COX-2 inhibitor class of drugs may be associated with a risk of thrombotic events (especially myocardial infarction (MI) and stroke), relative to placebo and some NSAIDs. *Renal effects:* Renal prostaglandins may play a compensatory role in the maintenance of renal perfusion. *Fluid retention, oedema and hypertension:* As with other medicinal products known to inhibit prostaglandin synthesis, fluid retention, oedema and hypertension have been observed in patients taking etoricoxib. *Hepatic effects:* Elevations of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (approximately three or more times the upper limit of normal) 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.

DRUG INTERACTIONS: *Oral anticoagulants:* In subjects stabilised on chronic warfarin therapy, the administration of etoricoxib 120 mg daily was associated with an approximate 13% increase in prothrombin time International Normalised Ratio (INR). Therefore, patients receiving oral anticoagulants should be closely monitored for their prothrombin time INR, particularly in the first few days when therapy with etoricoxib is initiated or the dose of etoricoxib is changed. *Diuretics, ACE inhibitors and Angiotensin II Antagonists:* NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g. dehydrated patients or

elderly patients with compromised renal function) the co-administration of an ACE inhibitor or Angiotensin II antagonist and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking etoricoxib concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. *Acetylsalicylic Acid*: In a study in healthy subjects, at steady state, etoricoxib 120 mg once daily had no effect on the anti-platelet activity of acetylsalicylic acid (81 mg once daily). Etoricoxib can be used concomitantly with acetylsalicylic acid at doses used for cardiovascular prophylaxis (low-dose acetylsalicylic acid). However, concomitant administration of low-dose acetylsalicylic acid with etoricoxib may result in an increased rate of GI ulceration or other complications compared to use of etoricoxib alone. Concomitant administration of etoricoxib with doses of acetylsalicylic acid above those for cardiovascular prophylaxis or with other NSAIDs is not recommended. *Cyclosporin and tacrolimus*: Although this interaction has not been studied with etoricoxib, coadministration of cyclosporin or tacrolimus with any NSAID may increase the nephrotoxic effect of cyclosporin or tacrolimus. Renal function should be monitored when etoricoxib and either of these drugs is used in combination. Pharmacokinetic interactions with Methotrexate, Oral contraceptives, Hormone Replacement Therapy (HRT), Prednisone/prednisolone, Digoxin, drugs metabolized by sulfotransferases, Ketoconazole, Voriconazole and Miconazole, Rifampicin and Antacids.

ADVERSE REACTIONS: alveolar osteitis, gastroenteritis, upper respiratory infection, urinary tract infection, anaemia (primarily associated with gastrointestinal bleeding), leukopenia, thrombocytopenia, hypersensitivity, oedema, appetite increase or decrease, weight gain, anxiety, depression, mental acuity decreased, hallucinations, dizziness, headache, dysgeusia, insomnia, paresthaesia/hypaesthesia, somnolence, blurred vision, conjunctivitis, tinnitus, vertigo, palpitations, arrhythmia, hypertension, flushing, cerebrovascular accident, transient ischaemic attack, hypertensive crisis, vasculitis, bronchospasm, cough, dyspnoea, epistaxis, abdominal pain, Constipation, flatulence, gastritis, heartburn/acid reflux, diarrhea, dyspepsia/epigastric discomfort, nausea, vomiting, oesophagitis, oral ulcer, abdominal distention, bowel movement pattern change, dry mouth, gastroduodenal ulcer, peptic ulcers including gastrointestinal perforation and bleeding, irritable bowel syndrome, pancreatitis, ALT increased, AST increased, ecchymosis, facial oedema, pruritus, rash, erythema, urticaria, muscular cramp/spasm, musculoskeletal pain/stiffness, proteinuria, serum creatinine increased, renal failure/renal insufficiency, asthenia/fatigue, flu-like disease, chest pain, blood urea nitrogen increased, creatine phosphokinase increased, hyperkalaemia, uric acid increased.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/ ETOXIB 60, 90, 120mg Tablet /Aug-22/02/ABPI

(Additional information is available on request)