ECOCIB®
ETORICOXIB TABLETS

Composition:
Each film coated Tablet contains: Etoricoxib 90mg.
Pharmacology:
Etoricoxib is a new COX-2 selective inhibitor. It's selectively inhibits isoform 2 of cyclo-oxygenases enzyme (COX-2) thus reducing prostaglandins (PGs) generation from arachidonic acid.
Cyclooxygenase is responsible for generation of prostaglandins. Two isoforms, COX-1 and COX-2, have been identified. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. COX-2 is also involved in ovulation, implantation and closure of the ductus arteriosus, regulation of renal function, and central nervous system functions (fever induction, pain perception and cognitive function). It may also play a role in ulcer healing. COX-2 has been identified in tissue around gastric ulcers in man but its relevance to ulcer healing has not been established.
Pharmacokinetics:
Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Following 120 mg once-daily dosing to steady state, the peak plasma concentration (geometric mean C_{max} = 3.6 µg/ml) was observed at approximately 1 hour (T_{max}) after administration to fasted adults. The geometric mean area under the curve ($AUC_{0\text{-}24hr}$) was 37.8 µghr/ml. The pharmacokinetics of etoricoxib are linear across the clinical dose range. Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 µg/ml. The volume of distribution at steady state (V_{dss}) was approximately 1,20l in humans. Etoricoxib is extensively metabolized with <1% of a dose recovered in urine as the parent drug. The major route of metabolism to form the 6'-hydroxymethyl derivative is catalyzed by CYP enzymes. Elimination of Etoricoxib occurs almost exclusively through metabolism followed by renal excretion.
Indications:
Ecocib tablet is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.
Ecocib tablet is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery.
Dosage & Administration:
Method of administration: For oral administration.
Osteoarthritis, rheumatoid arthritis (RA), Ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis:
One tablet once daily
Postoperative dental surgery pain: One tablet daily for 3 days.
In Acute gouty arthritis: One tablet twice daily for 8days
Contraindications:
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, Inflammatory
Bowel disease and Congestive heart failure.
Drug interactions:
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.
NSAIDs may reduce the effect of diuretics and other antihypertensive drugs.
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. Etoricoxib is an inhibitor of human sulfotransferase activity, particularly SULT1E1, and has been shown to increase the serum concentrations of ethinyl estradiol.
Co-administration of Etoricoxib with rifampicin, a potent inducer of CYP enzymes, produced a 65% decrease in etoricoxib plasma concentrations.
Pregnancy and lactation:
Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, etoricoxib must be discontinued. Etoricoxib is excreted in the milk of lactating rats. Women who use etoricoxib must not breast feed. The use of etoricoxib, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive.
Effects on ability to drive and use machines. Patients who experience dizziness, vertigo or somnolence while taking etoricoxib should refrain from driving or operating machinery
Side Effects:
The most common adverse effects include; alveolar osteitis oedema/fluid retention, dizziness, headache palpitations, arrhythmia, hypertension, bronchospasm abdominal pain, Constipation, flatulence, gastritis, heartburn/acid reflux, diarrhea, dyspepsia/epigastric discomfort, nausea, vomiting, oesophagitis , oral ulcer, ALT increased, AST increased, ecchymosis ,asthenia /fatigue and flu-like disease.
Other includes; atrial fibrillation, tachycardia, congestive heart failure, non-specific ECG changes, angina pectoris[‡], myocardial infarction, flushing, cerebrovascular accident[§], transient ischaemic attack, hypertensive crisis *and* vasculitis
Overdosage:
The most frequently observed adverse experiences were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, cardio renal events). 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. Etoricoxib is not dialysable by haemodialysis
Presentation:
Blister pack of 1 x 10`s per unit box.
Storage conditions:
Store in a dry place, below 30°C. Protect from light.
Keep all medicines out of reach of children.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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Ref: Lf /DL/Ecocib /01 Date of issue: September 2017