TORCOXIA BCD

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

Abbreviated Prescribing information for TORCOXIA BCD (Etoricoxib 60, 90 and 120 mg tablet) [Pleaserefer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Etoricoxib is a potent, orally active, highly selective cyclooxygenase-2 (COX-2) inhibitor within and above the clinical dose range.

INDICATION: For acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA), treatment of acute gouty arthritis, relief of acute pain, relief of chronic musculoskeletal pain.

DOSAGE AND ADMINISTRATION: Osteoarthritis: 60 mg once daily. Rheumatoid Arthritis: 90 mg once daily. Acute Gouty Arthritis: 20 mg once daily. Etoricoxib 120 mg should be used only for the acute symptomatic period. Acute Pain: 120 mg once daily. Chronic Musculoskeletal Pain: 60 mg once daily. Hepatic Insufficiency: if mild hepatic insufficiency, a dose of 60 mg once daily should not be exceeded. In moderate hepatic insufficiency, the dose should be reduced; a dose of 60 mg every other day should not be exceeded. Renal Insufficiency: In patients with advanced renal disease (creatinine clearance <30 mL/min), treatment with Etoricoxib is not recommended. No dosage adjustment is necessary for patients with lesser degrees of renal insufficiency (creatinine clearance 30 mL/min).

CONTRAINDICATION: in patients with hypersensitivity to any component of the product.

WARNINGS & PRECAUTIONS: In patients with advanced renal disease, treatment with TORCOXIA is not recommended. TORCOXIA should be used with caution in patients with considerable dehydration. Fluid retention, oedema and hypertension have been observed. Caution should be exercised in patients with a medical history of ischemic heart disease/cardiovascular disorder, GI perforation, ulcers and bleeding (PUB). Physicians should be aware that individual patients may develop upper gastrointestinal (GI) ulcers/ulcer complications irrespective of treatment. Elevations of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) have been reported. TORCOXIA should be used with caution in patients who have previously experienced acute asthmatic attacks, urticaria, or rhinitis. TORCOXIA may mask fever, which is a sign of infection. The physician should be aware of this when using TORCOXIA in patients being treated for infection. Use of TORCOXIA should be avoided in late pregnancy because it may cause premature closure of the ductus arteriosus.

DRUG INTERACTION: Warfarin: increase in prothrombin time. Rifampin: decrease in TORCOXIA plasma area under the curve (AUC). Angiotensin Converting Enzyme (ACE) Inhibitors: diminish the antihypertensive effect of ACE inhibitors. Lithium: increase plasma lithium levels. Oral Contraceptives: increase in ethinyl estradiol concentration should be considered. Methotrexate: Monitoring for methotrexate-related toxicity should be considered.

ADVERSE REACTIONS: Asthenia/fatigue, dizziness, dyspepsia, heartburn, nausea, headache, ALT increased, AST increased, hypersensitivity reactions, including anaphylactic/anaphylactoid reaction. Anxiety, insomnia, confusion, hallucinations, dysgeusia, somnolence, congestive heart failure, hypertensive crisis, bronchospasm. abdominal pain, oral ulcers, peptic ulcers including perforation and bleeding, vomiting, diarrhea, hepatitis, angioedema, rash, Stevens-Johnson syndrome pruritus, urticaria, renal insufficiency, including renal failure.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent house, Off Ashram road,
Ahmedabad - 380009, INDIA

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(Additional information is available on request)