

TOLDIN 400

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only
Abbreviated Prescribing information for TOLDIN (Etodolac 400mg tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Etodolac is a member of the pyranocarboxylic acid group of non-steroidal anti-inflammatory drugs (NSAIDs). The mechanism of action of etodolac is reported to be a preferential inhibitor of cyclo-oxygenase 2 (COX-2). **INDICATION:** For the relief of pain and inflammation in patients with rheumatoid arthritis and osteoarthritis. **DOSAGE AND ADMINISTRATION:** Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. After observing the response to initial therapy, the dose and frequency should be adjusted to suit an individual patient's needs. Etodolac tablets should be used with caution in patients with renal impairment. 1 tablet 2 to 3 times daily depending on patient's requirement for analgesia. **CONTRAINDICATION:** Etodolac is contraindicated in patients with known hypersensitivity to etodolac, asthma, urticaria, or other allergic-type reactions, history of gastrointestinal bleeding, severe heart failure, hepatic failure, renal failure, peptic ulceration or a history of peptic ulcer disease and in patients with cardiovascular risk. Not recommended for peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery and during the last trimester of pregnancy (risk of premature closure of the ductus arteriosus). **WARNINGS & PRECAUTIONS:** Increased risk of serious cardiovascular thrombotic events, hypertension, myocardial infarction (MI), and stroke, which can be fatal. Risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines (which can be fatal), rare cases of severe hepatic reactions including jaundice and fatal fulminant hepatitis, liver necrosis, borderline elevations of one or more liver tests and hepatic failure. NSAIDs inhibit platelet aggregation and prolong bleeding time. Patients with asthma may have aspirin-sensitive asthma. Because of cross reactivity, etodolac should not be administered to patients with this form of aspirin sensitivity. Risk of serious skin side effects such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which may be fatal and stop the drug immediately on development any type of rash. Patients should be informed of the warning signs and symptoms of hepatotoxicity and anaphylactoid reaction. Fluid retention and edema have been observed. In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis. Long-term administration has resulted in renal papillary necrosis and other renal injury. Risk of female fertility and is not recommended in woman attempting to conceive. **DRUG INTERACTION:** It can interact with ACE-inhibitors, Antacids, Aspirin, Cyclosporine, Digoxin, Methotrexate, furosemide and thiazides, Lithium, Phenylbutazone, Warfarin, Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs), Zidovudine, Mifepristone, Corticosteroids, Quinolone and antibiotics. The urine of patients who take etodolac can give a false-positive reaction for urinary bilirubin. **ADVERSE REACTIONS:** Abdominal pain, constipation, diarrhea, dyspepsia, flatulence, heartburn, nausea, vomiting, epigastric pain, indigestion, ulcerative stomatitis, haematemesis, melaena, rectal bleeding, vasculitis, abnormal renal function, fatigue, weakness/malaise, dizziness, elevated, headaches, pruritis, tinnitus, abnormal vision, pyrexia, drowsiness, bilirubinuria, hepatic function abnormalities, crohn's disease, nephrotoxicity, including interstitial nephritis, nephrotic syndrome, abnormal liver function, visual disturbances, optic neuritis, paraesthesia, thrombocytopenia, neutropenia,

agranulocytosis, aplastic anaemia, haemolytic anaemia, photosensitivity, dysuria, somnolence, insomnia, angioedema, photophobia and elevated BUN.

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ TOLDIN/400mg/Mar-15/01/AbPI

(Additional information is available on request)