

## TOLDIN ER 600

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

Abbreviated Prescribing information for **TOLDIN ER 600 [Etodolac Extended Release Tablets U.S.P.]**  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** All non-steroidal anti-inflammatory drugs (NSAIDs) have been shown to inhibit the formation of prostaglandins. Studies in human cell models have confirmed that etodolac is selective for the inhibition of COX-2.

**INDICATION:** - For Osteoarthritis and Rheumatoid Arthritis.

**DOSAGE AND ADMINISTRATION:** For oral administration. To be taken preferably with or after food. Undesirable effects may be minimised by using the shortest duration necessary to control symptoms. One tablet daily, taken with a glass of water.

**CONTRAINDICATION:** Hypersensitivity to etodolac or to any of the excipients, History of gastrointestinal bleeding or perforation, related to previous NSAID's therapy, Active or history of recurrent peptic ulcer/haemorrhage, Severe heart failure, hepatic failure and renal failure, During the last trimester of pregnancy.

**WARNINGS & PRECAUTIONS:** Patients on long-term treatment with Toldin ER 600 mg Tablets should be regularly reviewed as a precautionary measure e.g. for changes in renal function, haematological parameters, or hepatic function, Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Etodolac after careful consideration. Serious skin reaction 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 NSAID's. Use with caution in patients of bronchial asthma, systemic lupus erythematosus women who have difficulties conceiving, and GI bleeding, ulceration or perforation.

**DRUG INTERACTIONS:** Contraindicated with corticosteroids, warfarin, anti-hypertensives, mifepristone, quinolone, diuretics, cardiac glycosides, lithium, methotrexate, cyclosporin, Tacrolimus and zidovudine. **ADVERSE REACTIONS:** Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, asthma, aggravated asthma, bronchospasm or dyspnoea, or assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely exfoliative and bullous dermatoses, Oedema, pyrexia, weakness/malaise, dyspnoea, visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with existing auto-immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue, tremor, insomnia, drowsiness. Stevens - Johnson syndrome and Toxic Epidermal Necrolysis (very rare). Photosensitivity, thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia, abnormal liver function, hepatitis and jaundice, Bilirubinuria, urinary frequency, dysuria, nephrotoxicity in various forms including interstitial nephritis, nephrotic syndrome and renal failure.

### MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ TOLDIN ER 600mg /MAY-2016/01/ABPI

(Additional information is available on request)