TOLDIN P

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

Abbreviated Prescribing information for TOLDIN P (Etodolac 400 mg and Paracetamol 325 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Etodolac:** Etodolac is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities. **Paracetamol:** produces analgesic and antipyretic effect. It produces analgesia by raising pain threshold and the antipyretic effect is attributed to its ability to inhibit COX in the brain.

INDICATION: For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

DOSAGE AND ADMINISTRATION: Use the lowest effective dose for the shortest duration. After observing the response to initial therapy, the dose and frequency should be adjusted to suit an individual patient's needs. 1 tablet 2 to 3 times daily depending on patient's requirement for analgesia.

CONTRAINDICATION: In patients with known hypersensitivity to any of the ingredients. Etodolac should not be given to patients who have experienced asthma, urticaria, or other allergic-type reactions after taking other NSAIDs and history of gastrointestinal bleeding or perforation. Anaphylactic-like reactions have been reported. Contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Etodolac should not be used in patients with severe heart failure, hepatic failure, renal failure, active or history of recurrent peptic ulceration or a history of peptic ulcer disease and also during the last trimester of pregnancy. Paracetamol should not be given to patients with severe liver disease.

WARNINGS & PRECAUTIONS: **Etodolac:** NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction (MI), and stroke, which can be fatal. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Borderline elevations of one or more liver tests may occur. In addition, rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis, and hepatic failure have been reported. 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. Etodolac can cause serious skin side effects such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which may be fatal. Patients should be advised to stop the drug immediately if they develop any type of rash. Patients should be informed of the warning signs and symptoms of hepatotoxicity. Patients should be informed of the signs of an anaphylactoid reaction. Etodolac can lead to onset of new hypertension or worsening of pre-existing hypertension. Fluid retention and edema have been observed. Etodolac should be used with caution in patients with fluid retention or heart failure. In patients with systemic lupus erythematous (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis. Renal Effects: Long-term administration has resulted in renal papillary necrosis and other renal injury. Caution is required if etodolac is administered to patients suffering from, or with a history of, bronchial asthma. The use of etodolac may impair female fertility and is not recommended in woman attempting to conceive. In late pregnancy, the third trimester, etodolac should be avoided because it may cause premature closure of the ductus arteriosus. **Paracetamol:** Should be taken with caution in patients with impaired liver and kidney function. Not to be given to children under 6 years, without medical advice. Immediate medical advice should be sought in the event of an overdose, because of the risk of delayed, serious liver damage. Taking more than daily dose may cause serious liver damage or Allergic reactions.

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. Cholestyramine : The speed of absorption of paracetamol is reduced. Metoclopramide and Domperidone: The absorption of paracetamol is increased. Warfarin: The anticoagulant effect of warfarin may be enhanced.

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, paraethesia, Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia, haemolytic anaemia, photosensitivity and other allergic reactions occasionally.

MARKETED BY:

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(Additional information is available on request)