

PRESENTATION: Torax[®] 10 tablet: Each film coated tablet contains Ketorolac tromethamine USP 10 mg. Torax[®] 10 injection: Each 1 ml injection contains 10 mg ketorolac tromethamine USP. Torax[®] 30 injection: Each 1 ml injection contains 30 mg Ketorolac tromethamine USP. **PHARMACOLOGY:** Torax[®] is a potent analgesic of the non-steroidal anti-inflammatory drugs (NSAID). It inhibits the cyclo-oxygenase enzyme system and hence prostaglandin synthesis. Thus it gives minimal inflammatory effect at its analgesic effect. Torax[®] is not an anesthetic agent and possesses no sedative or anxiolytic properties; therefore it is not recommended as a pre-operative medication for the support of anesthesia when these effects are required. It is not an opioid and has no known effects on opioid receptors.

INDICATION: Torax[®] injections and tablets are indicated for the short-term management of moderate to severe acute post-operative pain. **DOSAGE & ADMINISTRATION:** Ketorolac tromethamine is for administration by intramuscular or bolus intravenous injection. The recommended initial dose of Ketorolac is 10 mg, followed by 10 to 30 mg every four to six hours as required. A total daily dose of 90 mg for non-elderly and 60 mg for the elderly, renally-impaired patients and patients less than 50 kg should not be exceeded. The maximum duration of treatment should not exceed two days. Ketorolac tablets are recommended for short-term use only (up to 7 days) and are not recommended for chronic use. 10mg every 4 to 6 hours as required. Doses exceeding 40 mg per day are not recommended. For patients receiving parenteral Ketorolac tromethamine, and who are converted to Ketorolac tromethamine oral tablets, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, renally-impaired patients and patients less than 50 kg) and the oral component should not exceed 40 mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

SIDE EFFECTS: Commonly occurring side-effects are nausea, vomiting, gastro-intestinal bleeding, melaena, peptic ulcer, pancreatitis, anxiety, drowsiness, dizziness, headache, hallucinations, excessive thirst, inability to concentrate, insomnia, malaise, fatigue, pruritus, urticaria, skin photosensitivity, Lyell's syndrome, Stevens-Johnson syndrome, flushing, bradycardia, hypertension, palpitations, chest pain, infertility in female, dyspnoea, asthma, pulmonary oedema, fever, injection site pain.

CONTRAINDICATION: Ketorolac tromethamine is contraindicated in patients having hypersensitivity to this drug or other NSAIDs and those patients in whom aspirin or other prostaglandin synthesis inhibitors induce allergic reactions. It is also contraindicated in a history of peptic ulcer or gastro-intestinal bleeding, moderate or severe renal impairment (serum creatinine > 160 micromol/l), a history of asthma, children under 16 years of age. Ketorolac tromethamine is contra-indicated as prophylactic analgesia before surgery due to inhibition of platelet aggregation and is contra-indicated intraoperatively because of the increased risk of bleeding. It is also contraindicated during pregnancy, labor, delivery or lactation.

DRUG INTERACTIONS: Ketorolac tromethamine should not be used with other NSAIDs or in patients receiving aspirin because of the potential for additive side-effects. Care should be taken when administering Ketorolac tromethamine with anti-coagulants since co-administration may cause an enhanced anti-coagulant effect. Ketorolac tromethamine and other non-steroidal anti-inflammatory drugs can reduce the anti-hypertensive effect of beta-blockers and may increase the risk of renal impairment when administered concurrently with ACE inhibitors, particularly in volume depleted patients. Caution is advised when methotrexate is administered concurrently, since some prostaglandin synthesis inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possibly enhance its toxicity. Probenecid should not be administered concurrently with ketorolac tromethamine because of increases in ketorolac plasma level and half-life.

PRECAUTION: Patients over the age of 65 years may be at a greater risk of experiencing adverse events than younger patients. Ketorolac tromethamine can cause gastro-intestinal irritation, ulcers or bleeding in patients with or without a history of previous symptoms. Bronchospasm may be precipitated in patients with a history of asthma. Since ketorolac tromethamine and its metabolites are excreted primarily by the kidney, patients with moderate to severe impairment of renal function (serum creatinine greater than 160 micromol/l) should not receive. Fluid retention and oedema have been reported with the use of Ketorolac tromethamine.

USE IN PREGNANCY & LACTATION: Safety in human pregnancy has not been established. Ketorolac has been detected in human milk at low levels. Ketorolac is therefore contraindicated during pregnancy, labour or delivery, or in mothers who are breast feeding.

STORAGE: Torax® tablet & injection should be store in a cool & dry place, protect from light & moisture.

HOW SUPPLIED: Torax® 10 tablet: Box containing 2x10 tablets in Alu-Alu pack. Torax® 10 injection: Box containing 1x5 ampoules in blister pack. Torax® 30 injection: Box containing 1x5 ampoules in blister pack.