Torax®

Ketorolac Trometamol

COMPOSITION

Torax® 10 tablet : Each film coated tablet contains Ketorolac Trometamol 10 mg.
Torax® 30 injection: Each 1 mL ampoule contains Ketorolac Trometamol 30 mg.
Torax® 60 injection: Each 2 mL ampoule contains Ketorolac Trometamol 60 mg.

INDICATION

Torax® injections and tablets are indicated for the short-term management of moderate to severe acute post-operative pain.

Pharmacology

Ketorolac is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits cyclooxygenase (COX-1 and COX-2), reducing prostaglandin synthesis. It provides potent analgesic, anti-inflammatory, and antipyretic effects. Commonly used for short-term management of moderate to severe pain, it has minimal sedative properties and carries risks of gastrointestinal, renal, and bleeding complications.

DOSAGE & ADMINISTRATION

Injections: For adult patients (<65 years)
Ketorolac Trometamol is for administration by intramuscular or bolus intravenous injection. Initial dose is 60 mg IM (single) or 30 mg IV(Single). Maintenance dose is 30 mg IM/IV 6 hourly. Maximum dose is 120 mg/day.
For elderly patients (>65 years), patients with renal Impairment & those weighing less than 50 kg.
Initial dose is 30 mg IM. Maintenance dose is 10-15 mg IM/IV 6 hourly. Maximum dose is 60 mg/day. The maximum duration of treatment should not exceed two days.

Tablet: Ketorolac Trometamol 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 Trometamol and who are converted to Ketorolac Trometamol 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 EFFECT

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 Trometamol 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.

Ketorolac Trometamol 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

WARNING & PRECAUTION

Patients over the age of 65 years may be at a greater risk of experiencing adverse events than younger patients. Ketorolac Trometamol can cause gastro-intestinal irritation, ulcers or bleeding in patients with or without a history of previous symptoms.
Since ketorolac Trometamol 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 Trometamol.

USE IN PREGNANCY & LACTATION

Safety in human pregnancy has not been established. Ketorolac Trometamol has been detected in human milk at low levels. Ketorolac Trometamol is therefore contraindicated during pregnancy, labor or delivery, or in mothers who are breast feeding.

USE IN CHILDREN & ADOLESCENT

There are no data available to support the use of ketorolac in pediatric patients. Studies on this medicine have been done only in adult patients, and there is no specific information comparing use of ketorolac in children up to 16 years of age with use in other age groups.

DRUG INTERACTION

Ketorolac Trometamol 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 Trometamol with anti-coagulants since co-administration may cause an enhanced anti-coagulant effect. Ketorolac Trometamol 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 Trometamol because it increases in ketorolac plasma level and half-life.

OVERDOSE

Common symptoms of ketorolac overdose include nausea, vomiting, epigastric pain, gastrointestinal bleeding, lethargy and drowsiness. More rare symptoms of overdose include acute renal failure, hypertension, respiratory depression, and coma.

STORAGE

Torax® tablet: Protect from light & moisture, store below 30°C. Keep out of reach of children.
Torax® Injection: Protect from light & moisture, store below 30°C. Keep out of reach of children.

HOW SUPPLIED

Torax® 10 tablet: Each Box contains 30 tablets in Alu-Alu blister pack.
Torax® 30 injection: Each Box contains 5 mini-cartons and each mini-carton contains 1 ampoule in blister pack with disposable syringe.
Torax® 60 injection: Each Box contains 1 ampoule in blister pack with a disposable syringe.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
Bangladesh