Torax®

Ketorolac tromethamine USP

PRESENTATION

Torax® 10 tablet : Each film coated tablet contains Ketorolac tromethamine USP 10 mg.
Torax® 30 injection: Each ml injection contains Ketorolac tromethamine USP 30 mg.
Torax® 60 injection: Each 2 ml injection contains Ketorolac tromethamine USP 60 mg.

INDICATION

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

DOSAGE & ADMINISTRATION

Injections: For adult patients (<65 years)
Ketorolac tromethamine 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 tromethamine 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 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 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.

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

DRUG INTERACTION

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 it 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.
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 tromethamine has been detected in human milk at low levels. Ketorolac tromethamine is therefore contraindicated during pregnancy, labour or delivery, or in mothers who are breast feeding.

STORAGE

Torax® tablet: store in a cool & dry place, protect from light & moisture.
Torax® Injection: store in a cool & dry place, protect from light.

HOW SUPPLIED

Torax® 10 tablet: Box containing 50 tablets in Alu-Alu pack.
Torax® 30 injection: Box containing 5 ampoules in blister pack (with disposable syringe).
Torax® 60 injection: Box containing 1 ampoule in blister pack and a disposable syringe (3 ml).

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH