Torax®

Ketorolac

COMPOSITION
Torax® 10 tablet: Each film coated tablet contains Ketorolac Trometamol Ph. Eur. 10 mg.
Torax® 30 injection: Each 1 ml ampoule contains Ketorolac Trometamol Ph. Eur 30 mg.

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
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-EFFECTS
Gastro-intestinal disturbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur. Systemic as well as local effects of NSAIDs contribute to gastrointestinal damage; taking oral formulations with milk or food, or using enteric-coated formulations, or changing the route of administration may only partially reduce symptoms such as dyspepsia. Other side-effects include hypersensitivity reactions (particularly rashes, angioedema, and bronchospasm), headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity, and haematuria. Blood disorders have also occurred. Fluid retention may occur (rarely precipitating congestive heart failure); blood pressure may be raised.

Renal failure may be provoked by NSAIDs, especially in patients with pre-existing renal impairment. Rarely, papillary necrosis or interstitial fibrosis associated with NSAIDs can lead to renal failure. Hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, visual disturbances, stevens-johnson syndrome, and toxic epidermal necrolysis are other rare side-effects. Induction of or exacerbation of colitis or crohn's disease has been reported.

Aseptic meningitis has been reported rarely with NSAIDs-patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible. Also gastro-intestinal disturbances, taste disturbances, dry mouth; flushing, bradycardia, palpitation, chest pain, hypertension, pallor; dyspnoea, asthma; malaise, euphoria, psychosis, paraesthesia, convulsions, abnormal dreams, hyperkinesia, confusion, hallucinations; urinary frequency, thirst, sweating; hyponatraemia, hyperkalaemia, myalgia; visual disturbances (including optic neuritis); purpura, pain at injection site.

CONTRAINDICATIONS
In allergic disorders (they are contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID-which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID), and in coagulation defects. All NSAIDs are contraindicated in severe heart failure. All NSAIDs (including cyclo-oxygenase-2 selective inhibitors) are contraindicated in patients with active gastrointestinal ulceration or bleeding. Piroxicam, ketoprofen, and ketorolac are contraindicated in patients with any history of gastrointestinal bleeding, ulceration, or perforation.
Other non-selective NSAIDs are contraindicated in patients with a history of recurrent gastrointestinal ulceration or haemorrhage (two or more distinct episodes), and in patients with a history of gastrointestinal bleeding or perforation related to previous NSAID therapy. Also complete or partial syndrome of nasal polyps; haemorrhagic diatheses (including coagulation disorders) and following operations with high risk of haemorrhage or incomplete haemostasis; confirmed or suspected cerebrovascular bleeding; hypovolaemia or dehydration.

Hepatic impairment
NSAIDs should be used with caution in patients with hepatic impairment; there is an increased risk of gastrointestinal bleeding and fluid retention. NSAIDs should be avoided in severe liver disease.

Renal impairment
Max. 60 mg daily by intramuscular or intravenous injection; avoid if serum creatinine greater than 160 micromol/litre; NSAIDs should be avoided if possible or used with caution in patients with renal impairment; the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored. Sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure; deterioration in renal function has also been reported after topical use.

CAUTION
NSAIDs should be used with caution in the elderly, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID), and in coagulation defects. Long-term use of some NSAIDs is associated with reduced female fertility, which is reversible on stopping treatment. Caution is also required in patients with connective-tissue disorders, In patients with cardiac impairment, caution is required.
In patients with cardiac impairment, caution is required since NSAIDs may impair renal function. They should be used with caution in patients with a history of cardiac failure, left ventricular dysfunction, hypertension, in patients with oedema for any other reason, and in patients with other risk factors for cardiovascular events. Other non-selective NSAIDs should be used with caution in uncontrolled hypertension, heart failure, ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, and when used long term in patients with risk factors for cardiovascular events.
While it is preferable to avoid NSAIDs in patients with active or previous gastro-intestinal ulceration or bleeding, and to withdraw them if gastro-intestinal lesions develop, nevertheless patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on NSAIDs for effective relief of pain and stiffness. Patients at risk of gastro-intestinal ulceration (including the elderly), who need NSAID treatment should receive gastroprotective treatment; for advice on the prophylaxis and treatment of NSAID-associated gastro-intestinal ulcers, NSAIDs should also be used with caution in Crohn's disease or ulcerative colitis, as these conditions may be exacerbated.

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, labour or delivery, or in mothers who are breast feeding.

STORAGE
Torax® tablet: Store below 30°C. Protect from light & moisture.
Torax® injection: Store below 30°C in dry place.
Keep away from light. Keep out of children's reach.

HOW SUPPLIED
Torax® 10 tablet: Box containing 1 x 10 / 2 x 10 / 5 x 10 / 6 x 10 / 10 x 10 tablets in Alu-Alu blister pack.
Torax® 30 injection: Box containing 1 x 1 / 1 x 5 / 2 x 5 / 3 x 5 ampoules in blister pack with / without disposable syringe.

SQUARE