Toralin

Ketorolac Tromethamine USP

COMPOSITION

Toralin Tablet: Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.
Toralin 30 IV/IM Injection: Each 1 ml ampoule contains sterile solution of Ketorolac Tromethamine USP 30 mg.
Toralin 60 IM Injection: Each 2 ml ampoule contains sterile solution of Ketorolac Tromethamine USP 60 mg.

PHARMACOLOGY

Ketorolac Tromethamine is a nonsteroidal anti-inflammatory drug (NSAID). It acts as peripherally-acting analgesic. It inhibits the cyclo-oxygenase enzyme system and hence synthesis of prostaglandins. It does not have known effects on opiate receptors.

INDICATIONS

It is indicated for the short-term (≤5 days) management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting. Therapy should always be initiated with intravenous or intramuscular dosing of Ketorolac Tromethamine and oral Ketorolac Tromethamine is to be used only as continuation treatment, if necessary.

The total combined duration of use of Ketorolac Tromethamine injection and oral Ketorolac Tromethamine is not to exceed 5 days of use because of the potential of increasing the frequency and severity of adverse reactions associated with the recommended doses. Patients should be switched to alternative analgesics as soon as possible, but Ketorolac Tromethamine therapy is not to exceed 5 days.

DOSAGE AND ADMINISTRATION

Injection:
When administering injection, the intravenous bolus must be given over no less than 15 seconds. The intramuscular administration should be given slowly and deeply into the muscle.
Single-Dose Treatment (IV/IM)
Patients <65 years of age: One dose of 60 mg as IM or One dose of 30 mg as IV/IM.
Patients ≥65 years of age, renally impaired and/or <50 kg of body weight: One dose of 30 mg as IV/IM or One dose of 15 mg as IV.
Multiple-Dose Treatment (IV/IM)
Patients <65 years of age: 30 mg every 6 hours. The maximum daily dose should not exceed 120 mg.
Patients ≥65 years of age, renally impaired and/or <50 kg of body weight: 15 mg every 6 hours. The maximum daily dose should not exceed 60 mg.

For breakthrough pain, do not increase the dose or the frequency of Ketorolac Tromethamine. Consideration should be given to supplementing these regimens with low doses of opioids "as needed" unless contraindicated.

Tablet:
Patients <65 years of age: 10 mg every 4 to 6 hours. Doses exceeding 40 mg per day are not recommended.
Patients ≥65 years of age: 10 mg every 6 to 8 hours. Daily doses of 30-40 mg per day should not be exceeded.

Conversion from Intramuscular to Oral Therapy
For patients being converted from IM to oral, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, mild renally-impaired patients and patients weighing less than 50 kg) and the oral component should not exceed 40 mg (30-40 mg for the elderly) on the day the change of formulation is made.

Ketorolac Tromethamine injection should not be mixed in a small volume (e.g., in a syringe) with morphine sulfate, meperidine hydrochloride, promethazine hydrochloride or hydroxyzine hydrochloride; this will result in precipitation of ketorolac from solution.

CONTRAINDICATIONS

Ketorolac Tromethamine is contraindicated in patients with known hypersensitivity to the drug. It is also contraindicated in patients with active peptic ulcer disease, a history of peptic ulcer disease, or gastrointestinal bleeding. It should not be administered to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Ketorolac Tromethamine is contraindicated as a prophylactic analgesic before any major surgery, in CABG (Coronary Artery Bypass Graft) surgery, in patients with advanced renal impairment or those at risk for renal failure, during labor and delivery, and in patients with cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, or those at high risk of bleeding. It is also contraindicated in patients currently receiving aspirin or other NSAIDs.

WARNING AND PRECAUTION

The most serious risks associated with Ketorolac Tromethamine include gastrointestinal effects like ulceration, bleeding and perforation, which can be minimized by using the lowest effective dose for the shortest duration. It should be avoided peri-operatively due to hemorrhage risk and used cautiously postoperatively when hemostasis is critical. For cardiovascular thrombotic events, use the lowest effective dose for the shortest duration. In post-MI patients, monitor for signs of cardiac ischemia. Blood pressure should be closely monitored during initiation and throughout NSAID therapy, especially in patients with hypertension. Patients with impaired renal function should be closely monitored and use in severe heart failure should be avoided unless the benefits outweigh the risks; if used, monitor for worsening heart failure. Caution is advised in patients with impaired hepatic function or liver disease and in those with pre-existing asthma. Serious skin reactions like exfoliative dermatitis, SJS and TEN require immediate discontinuation if any rash or hypersensitivity occurs. If signs of DRESS appear, stop the drug and evaluate the patient immediately.

SIDE EFFECTS

The most common side effects include nausea, dyspepsia, gastrointestinal pain, bleeding or perforation, drowsiness, headache, hypertension, edema and injection site pain.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies of Ketorolac Tromethamine in pregnant women. Ketorolac Tromethamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Exercise caution when ketorolac is administered to a nursing woman.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of Ketorolac Tromethamine in pediatric patients below the age of 17 years have not been established.

DRUG INTERACTIONS

Warfarin, Digoxin, Salicylates and Heparin: Use with extreme caution in concomitant use and closely monitor the patients.
Aspirin: Concomitant use increased risk of adverse effects.
Diuretics: Closely monitored for signs of renal failure during concomitant use.
Probenecid: Concomitant use with Ketorolac Tromethamine is contraindicated.
Lithium: Patients should be carefully monitored for signs of lithium toxicity.
Methotrexate: Use caution when NSAIDs are administered concurrently with methotrexate.
ACE Inhibitors/Angiotensin II Receptor Antagonists: May increase the risk of renal impairment.
Antiepileptic Drugs (Phenytoin, Carbamazepine): Sporadic cases of seizures have been reported with concurrent use.
Psychoactive Drugs (Fluoxetine, Thiothixene, Alprazolam): Hallucinations have been reported with concurrent use.
Pentoxifylline: There is an increased risk of bleeding.
Selective Serotonin Reuptake Inhibitors (SSRIs): Caution is advised when used concurrently with SSRIs.

OVERDOSAGE

Patients should be managed by symptomatic and supportive care following overdose. There are no specific antidotes.

STORAGE

Toralin Tablet: Store below 30°C temperature in a cool and dry place. Protect from light and moisture.
Toralin Injection: Store below 30°C temperature in a cool and dry place. Protect from light. Do not freeze.

Keep out of the reach of children.

HOW SUPPLIED

Toralin Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.
Toralin 30 IV/IM Injection: Each box contains one ampoule containing sterile solution of Ketorolac Tromethamine USP 30 mg in Alu-PVC blister, a sterile disposable syringe (3 ml) and an alcohol pad.
Toralin 60 IM Injection: Each box contains one ampoule containing sterile solution of Ketorolac Tromethamine USP 60 mg in Alu-PVC blister, a sterile disposable syringe (3 ml) and an alcohol pad.

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Manufactured by:
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NIPRO JMI Pharma