KETOROLAC TROMETHAMINE

ORADOL
30 mg/mL Solution for Injection
Non-steroidal Anti-Inflammatory

FORMULATION:
Each mL contains:
Ketorolac Tromethamine.................................30 mg

PHARMACOKINETICS:
Ketorolac trometamol is absorbed after intramuscular or oral doses. At physiological pH ketorolac trometamol dissociates to form an anionic ketorolac molecule which is less hydrophilic than the trometamol salt. The peak plasma concentration of ketorolac is reached within about 30 to 60 minutes; absorption after intramuscular injection may be slower than that after oral doses in some individuals. Ketorolac is over 99% bound to plasma proteins. It does not readily penetrate the blood-brain barrier. Ketorolac crosses the placenta and small amounts of drug are distributed into breast milk. The terminal plasma half-life is about 4 to 6 hours, but is about 6 to 7 hours in the elderly and 9 to 10 hours in patients with renal dysfunction. The major metabolic pathway is glucuronic acid conjugation; there is some para-hydroxylation. About 90% of a dose is excreted in urine as unchanged drug and conjugated and hydroxylated metabolites, the remainder is excreted in the faeces.

INDICATIONS:
Used in the short-term management of moderate to severe post-operative pain.

DOSAGE AND ADMINISTRATION:
The recommended initial dose of Ketorolac tromethamine IV is 10mg followed by 10-30mg every 4-6 hours as maintenance dose, but minimum effective dose is recommended. The duration of treatment should not be longer than 2 days. Daily dose should not exceed 90mg for non-elderly and 60mg for elderly, renal impaired patients and patients with body weight less than 50kg.

The dose or administration intervals can be adjusted according to the severity of the symptoms and pain or as prescribed by the physician.

PRECAUTIONS:
The patients who drink more than 3 glasses of alcohol every day should consult a doctor when they take ketorolac tromethamine or other NSAID ulcer bleeding may be induced gastric ulceration, bleeding, perforation may occur. A various side effect including interstitial nephritis and acute renal insufficiency may occur, caution for the patients with renal disease. Bleeding may occur. Hypersensitivity to any component of this product. Ketorolac tromethamine should not be given concomitantly with other NSAIDs.

CONTRAINDICATIONS:
1. Patients with peptic ulcers or history of ulcers and perforation.
2. Patients with gastric bleeding of its history
3. Patients with pre-disposition of bleeding or bleeding history
4. Patients with cerebrovascular bleeding suspicion of cerebrovascular bleeding or its history
5. Patients with high risk of bleeding postoperatively
6. Patients with moderate to severe renal insufficiency (serum creatine 160 mol/l
7. Patients with bronchial asthma or its history
8. Patients with volume depletion or dehydration
9. Patients with hypersensitivity to ketorolac tromethamine, aspirin or other NSAIDs
10. Patients with nasal polyp, angioedema or symptoms of bronchospasms
11. Woman of pregnancy and lactation
12. Patients being treated with other NSAIDs
13. Patient treated with anticoagulant, pentoxifyline, probenecid or lithium.
14. Patients who have undergo tonsillotomy
15. Children under 2 years of age.

ADVERSE EFFECTS:
1. GI Tract: nausea, dyspepsia, GI pain, diarrhea, occasional constipation, flatulence, GI coolness, vomiting, stomatitis, peptic ulcer, GI bleeding, perforation, melena, rectal bleeding, gastritis, eructation, anorexia, increased appetite and pancreatitis may rarely occur.
2. CVS: hypertension, flushing, palpitation, pallor, hypotension, syncope, bradycardia and cardiagra may rarely occur.
3. Nervous system: headache, sweating, occasionally dizziness, convulsion, vertigo, tremor, hallucination, abnormal dreams, euphoria, extra-pyramidal syndrome, paresthesia, depression, insomnia, nervousness, dry mouth, excessive thirst, abnormal thinking, inability to concentrate, hyperkinesia, stupor, myalgia, aseptic meningitis, stupor, myalgia, aseptic meningitis, stupor, myalgia, aseptic meningitis, stupor, myalgia, aseptic meningitis, stupor, myalgia, aseptic meningitis, stupor, myalgia, aseptic meningitis.

CAUTION:
Foods, Drugs, Devices, and Cosmetics ct prohibits dispensing without prescription.

STORAGE:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
1ml Amber Glass Ampoule USP Type-I Box x 1’s

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