Ketorolac Tromethamine Injection, USP
For IM or SC use only

**WARNINGS**

**Drug Interactions**

- **Oral Anticoagulants**: The concurrent use of ketorolac tromethamine and oral anticoagulants may lead to an increased risk of bleeding. Close monitoring of the patient's coagulation status is recommended.

- **Use in the Elderly**: Use ketorolac tromethamine cautiously in elderly patients, as they may be more susceptible to the risks of bleeding and renal impairment.

**PRECAUTIONS**

- **Pre-existing Asthma**: Ketorolac tromethamine has been shown to cause bronchospasm in patients with a history of asthma or reactive airway disease. Consider alternative analgesics in these patients.

- **Diabetes**:

  - **Rare Case Reports**: Adverse events such as hyperglycemia and diabetes mellitus have been reported in patients treated with ketorolac tromethamine. Close monitoring of blood glucose levels is recommended.

- **Hepatitis**: A rare case report describes a patient with hepatitis who developed severe hepatic failure after a single dose of ketorolac tromethamine.

**OVERDOSAGE**

**Cardiovascular Effects**

- **Heart Failure**: In patients with heart failure, ketorolac tromethamine may cause a dose-dependent reduction in cardiac output, leading to decreased renal perfusion and increased risk of renal dysfunction.

**GI Effects**

- **Gastrointestinal Ulceration**: Ketorolac tromethamine has been associated with increased risk of gastrointestinal bleeding and ulceration. Use with caution in patients with a history of gastrointestinal disease.

**Hematologic Effects**

- **Anemia**: Anemia may occur in patients treated with ketorolac tromethamine, particularly in those with underlying renal insufficiency or malnutrition.

**Skin Effects**

- **Drug Rash**: A case report describes a patient with a drug rash who developed a severe cutaneous reaction after a single dose of ketorolac tromethamine.

**Special Populations**

- **Renal Insufficiency**: In patients with underlying renal insufficiency, ketorolac tromethamine clearance may be decreased, increasing the risk of toxicity. Use with caution and monitor closely.

**Adverse Reactions**

- **Common**: Headache, dizziness, nausea, vomiting, and abdominal pain are common adverse effects of ketorolac tromethamine.

**Dosage and Administration**

- **Initial Dose**: For adults, the initial dose is 30 mg IM or SC, repeated at 4-hour intervals as needed, not to exceed 150 mg/day.

**Pharmacokinetics**

- **Exposure**: The mean maximum plasma concentration (Cmax) of ketorolac tromethamine following complete distribution was 0.34 ± 0.14 mcg/mL on Day 1 and 0.64 ± 0.26 mcg/mL on Day 5.

- **Trough Levels**: Trough levels averaged 0.29 mcg/mL (SD ± 0.13) on Day 1 and 0.55 mcg/mL (SD ± 0.21) on Day 5.

**Contraindications**

- **Active Peptic Ulcer Disease**: Ketorolac tromethamine is contraindicated in patients with active peptic ulcer disease.

- **Renal Insufficiency**: Use with caution in patients with renal insufficiency, as clearance may be decreased.

- **Hydrocephalus and Intracranial Hemorrhage**: Ketorolac tromethamine is contraindicated in patients with hydrocephalus and intracranial hemorrhage.

**Warnings and Precautions**

- **Bleeding Risk**: Use with caution in patients with a history of bleeding or those at increased risk of bleeding.

- **Renal Effects**: Use with caution in patients with pre-existing renal impairment.

**Adverse Reactions**

- **Common**: Headache, dizziness, nausea, vomiting, and abdominal pain are common adverse effects of ketorolac tromethamine.
Studies indicate that, at therapeutic concentrations of warfarin, digoxin, salicylate, and heparin, ketorolac tromethamine may interfere with the anticoagulant effects of these drugs.  The concurrent use of ketorolac tromethamine with warfarin, digoxin, salicylate, and heparin requires careful monitoring of the anticoagulant effects of these drugs.

The effects of warfarin and NSAIDs, in general, on GI bleeding are synergistic, such that the users of both drugs together have a risk of serious GI bleeding higher than the users of either drug alone.  Although GI bleeding is a concern, NSAIDs are frequently used in patients with rheumatoid arthritis and other chronic conditions that require concomitant use with anticoagulants.

Ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair platelet function and platelet agglutination.  It is also a risk factor for arterial and/or venous thrombosis.  The risk of thrombotic events may also be increased by baseline risk factors such as hypertension, hyperlipidemia, or diabetes mellitus.

Reproduction studies have been performed during organogenesis using daily oral doses of ketorolac tromethamine tablets and solutions of ketorolac tromethamine injection and have revealed no evidence of harm to the fetus when administered at human therapeutic doses.  This drug is not a teratogen and is not expected to cause birth defects or other fetal abnormalities.  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.

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