Ketorolac Tromethamine Injection, USP

WARNINGS

Ketorolac tromethamine, a nonsteroidal anti-inflammatory drug (NSAID), is indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level. Oral ketorolac tromethamine is indicated only as continuation therapy to ketorolac tromethamine injection. The total combined duration of use of oral ketorolac tromethamine and IV or IM dosing of ketorolac tromethamine is not to exceed 5 days in which ketorolac tromethamine is not indicated for use in patients with active peptic ulcer disease.

The most serious risks associated with ketorolac tromethamine are:

- Gastrointestinal Effects
- Perioperative Hemorrhage

Ketorolac tromethamine is contraindicated in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV events in patients treated with ketorolac tromethamine. In postmarketing experience, postoperative hematomas and other signs of wound bleeding have been reported in association with the use of ketorolac tromethamine. Therefore, ketorolac tromethamine should be used with caution in patients with a recent MI, because CV events are more frequent in patients with active coronary artery disease, percutaneous coronary intervention, or coronary artery bypass graft surgery (see WARNINGS and PRECAUTIONS: Preexisting Asthma).

Ketorolac tromethamine should be used with caution in patients receiving concurrent anticoagulants, antiplatelet agents, or fibrinolytic therapy (see WARNINGS, Hemorrhage, and PRECAUTIONS: Preexisting Asthma).

Ketorolac tromethamine should be used with caution in patients receiving ACE inhibitors, angiotensin receptor blockers, or diuretics. This combination may result in an additive decrease in blood pressure (see WARNINGS, Hemorrhage, and PRECAUTIONS: Preexisting Asthma). Neutropenia is a very rare event with ketorolac tromethamine and has been reported in a small number of patients treated with IV ketorolac tromethamine (see PRECAUTIONS: Laboratory Tests). Ketorolac tromethamine is contraindicated for neuraxial (epidural or intrathecal) administration due to its alcohol content. Ketorolac tromethamine is contraindicated for neuraxial administration because of the potential of increasing the frequency and severity of adverse reactions associated with the use of ketorolac tromethamine and other NSAIDs (see WARNINGS, PRECAUTIONS: Preexisting Asthma, and ADVERSE REACTIONS). Patients with a recent MI (within 1 month) or recent CV surgery (within 6 months) are at particularly high risk. Ketorolac tromethamine injection is contraindicated in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure.

Abuse, Dependence, and Misuse

Abuse of ketorolac tromethamine may result in fatal overdose (see WARNINGS, Hemorrhage). Ketorolac tromethamine, a potent analgesic, is very easily abused. Accidental overdose is more likely to occur in patients with severe pain, such as postoperative pain. Ketorolac tromethamine is contraindicated in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure.
Sodium retention in patients receiving ketorolac tromethamine, because it can cause serious renal adverse events such as tubular necrosis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed of the signs of an anaphylactoid reaction (e.g., difficulty breathing, swelling of the face or throat). If these occur, patients should ask for medical advice when observing any indicative signs or symptoms. Patients should be advised to stop the drug and seek medical advice if they develop treatment-related adverse events, and advise patients not to give oral ketorolac tromethamine to other individuals.

Information for Patients

Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established. Studies in pediatric patients have shown that ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults.

Warnings: General

Hematological Adverse Effects

Adverse effects have been reported in patients receiving NSAIDs, including ketorolac tromethamine. This may be due to failure to monitor, confusion, or bias. Clinical hematological abnormalities may progress, may remain unchanged, or may be transient with continued therapy. Nucleated red blood cells of LYM (E) type may appear. Additional laboratory tests should be performed on selected patients (in approximately 1% of patients) in clinical trials with NSIDs. In addition, cases of severe hepatic reactions, including jaundice and fulminant hepatic failure, hepatitis and necrosis, and some with fatal outcomes have been reported.

A patient with a past and/or present history of unusual bleeding, or in whom an abnormal bleeding pattern has occurred, should be assessed for hemorrhage or thrombosis.

Pharmacokinetics

Ketorolac tromethamine, like other NSAIDs, can cause serious skin side effects such as bullous or necrotizing dermatitis, which may result in hospitalization and, in some cases, death. Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

Drug Interactions

Ketorolac tromethamine, like other NSAIDs, can cause serious skin side effects such as bullous or necrotizing dermatitis, which may result in hospitalization and, in some cases, death. Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.

	n the use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended for use in women of childbearing potential. Ketorolac tromethamine is not indicated for use in pregnant women. Ketorolac tromethamine is not associated with an increased risk of gastrointestinal toxicity, but it may be less effective in reducing fever and pain in these children than in adults. Ketorolac tromethamine is not recommended for use in patients with a history of aspirin-induced asthma, because ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) and is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients younger than 12 years of age have not been established.