FRESENIUS KABI

Ketorolac

Tromethamine Injection, USP

30 mg per 1 mL Simplist® ready-to-administer* prefilled syringe +RFID® is available from Fresenius Kabi.

- 36-month shelf life
- Manufacturer-embedded RFID tag
- Interoperable

*Medications that are administered intramuscularly require a needle be attached to the syringe.

Ketorolac Tromethamine Injection, USP

IMPORTANT SAFETY INFORMATION:

WARNING

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 treatment following intravenous or intramuscular dosing of ketorolac tromethamine, if necessary. The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed 5 days.

Ketorolac tromethamine is not indicated for use in pediatric patients and it is NOT indicated for minor or chronic painful conditions. Increasing the dose of ketorolac tromethamine beyond the label recommendations will not provide better efficacy but will increase the risk of developing serious adverse events.

GASTROINTESTINAL RISK

- Ketorolac tromethamine can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, ketorolac tromethamine is CONTRAINDICATED in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding.
  Elderly patients are at greater risk for serious gastrointestinal events (see **WARNINGS**).

CARDIOVASCULAR THROMBOTIC EVENTS

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use (see **WARNINGS** and **PRECAUTIONS**).
- Ketorolac tromethamine is CONTRAINDICATED in the setting of coronary artery bypass graft (CABG) surgery (see **CONTRAINDICATIONS and WARNINGS**).

RENAL RISK

- Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion (see **WARNINGS**).

RISK OF BLEEDING

- Ketorolac tromethamine inhibits platelet function and is, therefore, CONTRAINDICATED in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding (see **WARNINGS** and **PRECAUTIONS**).

Ketorolac tromethamine is CONTRAINDICATED as prophylactic analgesic before any major surgery.

HYPERSENSITIVITY

- Hypersensitivity reactions, ranging from bronchospasm to anaphylactic shock, have occurred and appropriate counteractive measures must be available when administering the first dose of ketorolac tromethamine injection (see **CONTRAINDICATIONS** and **WARNINGS**). Ketorolac tromethamine is CONTRAINDICATED in patients with previously demonstrated hypersensitivity to ketorolac tromethamine or allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).

INTRATHECAL OR EPIDURAL ADMINISTRATION

- Ketorolac tromethamine is CONTRAINDICATED for intrathecal or epidural administration due to its alcohol content.

RISK DURING LABOR AND DELIVERY

- The use of ketorolac tromethamine in labor and delivery is CONTRAINDICATED because it may adversely affect fetal circulation and inhibit uterine contractions.

CONCOMITANT USE WITH NSAIDs

- Ketorolac tromethamine is CONTRAINDICATED in patients currently receiving aspirin or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects.

SPECIAL POPULATIONS

- Dosage should be adjusted for patients 65 years or older, for patients under 50 kg (110 lbs) of body weight (see **DOSAGE AND ADMINISTRATION**) and for patients with moderately elevated serum creatinine (see **WARNINGS**). Doses of ketorolac tromethamine injection are not to exceed 60 mg (total dose per day) in these patients.

DOSAGE AND ADMINISTRATION

Ketorolac Tromethamine Tablets

- Ketorolac tromethamine tablets are indicated only as continuation therapy to ketorolac tromethamine injection, and the combined duration of use of ketorolac tromethamine injection and ketorolac tromethamine tablets is not to exceed 5 (five) days, because of the increased risk of serious adverse events.
- The recommended total daily dose of ketorolac tromethamine tablets (maximum 40 mg) is significantly lower than for ketorolac tromethamine injection (maximum 120 mg) (see **DOSAGE AND ADMINISTRATION**).

Contraindications - see BOXED WARNING. Additional contraindication(s): The concomitant use of ketorolac tromethamine with probenecid or pentoxifylline

Gastrointestinal Effects: Ketorolac tromethamine can cause serious GI adverse events including bleeding, ulceration, and perforation of the stomach, small intestine,

or large intestine, which can be fatal. To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest possible duration.

Hemorrhage: Patients on therapeutic doses of anticoagulants (e.g., heparin or dicumarol derivatives) have an increased risk of bleeding complications. Administer concomitant therapy cautiously and monitor closely.

Renal Effects: Renal toxicity has been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state. With the use of ketorolac tromethamine, there have been reports of acute renal failure, interstitial nephritis, and nephrotic syndrome.

Avoid the use of Ketorolac Tromethamine Injection, USP in patients with a recent myocardial infarction unless the benefits are expected to outweigh the risk of recurrent cardiovascular (CV) thrombotic events. If used, monitor patients for signs of cardiac ischemia.

Hypertension: Can lead to onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Monitor blood pressure.

Heart Failure and Edema: Fluid and NaCl retention, edema, oliguria, elevation of serum urea nitrogen and creatinine have been reported. Use cautiously in patients with cardiac decompensation, hypertension, or similar conditions.

Skin Reactions: Serious skin adverse events, such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, may occur without warning and can be fatal. Inform patients about signs and symptoms and discontinue the drug at the first appearance of skin rash or any other sign of hypersensitivity.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as ketorolac tromethamine injection. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis and may resemble an acute viral infection. Eosinophilia is often present. If such signs or symptoms are present, discontinue ketorolac tromethamine injection and evaluate the patient immediately.

Fetal Toxicity: Premature Closure of the Fetal Ductus Arteriosus: NSAIDs including ketorolac tromethamine injection, increase the risk of premature closure of the fetal ductus arteriosus in pregnant women at about 30 weeks gestation and later. Avoid use of ketorolac tromethamine injection in these patients. Oligohydramnios/Neonatal Renal Impairment: Use of NSAIDs, including ketorolac tromethamine injection, at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. If NSAID treatment is necessary between about 20 weeks and 30 weeks gestation, limit ketorolac tromethamine injection use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if ketorolac tromethamine injection treatment extends beyond 48 hours. Discontinue ketorolac tromethamine injection if oligohydramnios occurs and follow up according to clinical practice.

Hepatic Effects: Elevation of ALT or AST, jaundice, fatal fulminant hepatitis, liver necrosis, hepatic failure, and anemia have been reported. Monitor closely.

Pregnancy: Use of NSAIDs, including ketorolac tromethamine injection, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of ketorolac tromethamine injection use between about 20 and 30 weeks of gestation and avoid ketorolac tromethamine injection use at about 30 weeks of gestation and later in pregnancy.

Pediatric Use: Ketorolac Tromethamine is not indicated for use in pediatric patients. The safety and effectiveness of Ketorolac Tromethamine in pediatric patients below the age of 17 have not been established.

Adverse reaction rates increase with higher doses of ketorolac tromethamine. Severe adverse reactions include (also see Boxed Warning): GI ulceration, bleeding and perforation, postoperative bleeding, acute renal failure, anaphylactic and anaphylactoid reactions, and liver failure. Most common adverse reactions: Abdominal pain, constipation/diarrhea, dyspepsia, flatulence, GI fullness, GI ulcers, gross bleeding/perforation, heartburn, nausea, stomatitis, vomiting, abnormal renal function, anemia, dizziness, drowsiness, edema, elevated liver enzymes, headaches, hypertension, increased bleeding time, injection site pain, pruritus, purpura, rashes, tinnitus, sweating.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Ketorolac tromethamine 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.

For intravenous/intramuscular use (15 mg/mL and 30 mg/mL)

For intramuscular use only (60 mg/2 mL (30 mg/mL))

This important safety information does not include all the information needed to use Ketorolac Tromethamine Injection, USP safely and effectively. Please see accompanying full prescribing information, including BOXED WARNING, for KETOROLAC TROMETHAMINE INJECTION, USP. Full prescribing information is also available at www.simplist-us.com.

Simplist®

Ketorolac
Tromethamine Injection, USP

Strength	30 mg per 1 mL
Concentration	30 mg per mL
Fill volume	1 mL
Description	Single Dose Simplist® Prefilled Syringe
Unit of sale NDC	76045-209-10
Unit of sale bar code	N(01)30376045209106
Pack size	24 per Carton
Secondary packaging	Blister
Blister dimensions	4.449" x 1.063"
Carton dimensions	4.941" x 2.402" x 6.614"

Wholesale numbers

AmerisourceBergen	10260351
Cardinal	5902622
McKesson	2345007
Morris & Dickson	104943

To place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | www.plusRFID.com

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Please see full prescribing information, including BOXED WARNING, for Ketorolac Tromethamine Injection, USP at www.simplist-us.com.