These NSAID-related complications can be serious in ulceration, bleeding and perforation, postoperative bleeding, acute renal failure, anaphylactic and extreme caution and reduced dosages (see Risk of Ulceration, Bleeding, and Perforation).

Gastrointestinal:
- hematemesis
- hepatitis
- increased appetite
- jaundice
- melena
- rectal bleeding

Dermatologic:
- dry skin
- rash

Special Senses:
- dizziness
- hearing loss

Respiratory:
- chest pain
- dyspnea
- hyperventilation
- peptic ulcers and/or erosive gastritis and renal dysfunction

Other side effects include:
- heart attack
- stroke
- high blood pressure
- heart failure
- kidney problems including kidney failure
- breathing problems
- low blood urea nitrogen (BUN)
- low blood creatinine (Cr)
- breathing problems
- kidney problems
- swelling of the face or throat
- chest pain
- shortness of breath or trouble breathing
- peptic ulcers
- vomiting

 NSAID medicines should never be used right before an operation or a procedure. Ulcers and bleeding:
- ulcers
- stomach pain
- gas
- anemia
- dizziness

Get emergency help right away if you have any of the following symptoms:
- chest pain
- shortness of breath or trouble breathing

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:
- vomiting
- diarrhea
- high temperature
- unusual bleeding
- abnormal urination
- numbness or weakness in your arm or leg
- vision changes
- problems with memory (new)
- severe rash

What are NSAIDs?
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

These are not all the side effects with NSAID medicines.

What should I watch for while taking a NSAID medicine?
- bleeding problems
- stomach problems
- other serious problems

NSAIDs can cause serious bleeding problems, including stomach ulcers and bleeding, in some people. These problems can occur without warning and can cause death. See Risk of Ulceration, Bleeding, and Perforation.

Who should not take a NSAID medicine?
- Patients who had an allergic reaction to a NSAID medicine
- Patients who had an allergic reaction to sulindac (Clinoril, Sulofox)
- Patients who had an allergic reaction to aspirin or other non-aspirin-containing NSAIDs
- Patients who had an allergic reaction due to aspirin-induced asthma
- Have heart or blood vessel disease
- Have a history of stomach bleeding or ulcers
- Have ulcers or other stomach problems
- Have liver or kidney disease
- Are allergic to any medicine

This guide has been approved by the U.S. Food and Drug Administration.

Ketorolac Tromethamine Injection, USP

For IV use only (1 mg and 30 mg)

For Use Only by PROFESSIONAL PROVIDERS

Do not use this medicine if:
- you are allergic to ketorolac tromethamine
- you are allergic to salicylates
- you have asthma
- you have a history of sensitivity to aspirin

Call your doctor for medical advice about side effects. You may report side effects to the U.S. Food and Drug Administration at 1-800-FDA-1088. For more information go to www.hospira.com or call 1-877-855-VLAD. The Medication Guide has been approved by the U.S. Food and Drug Administration. Revised 12/2011

Hospira, Inc., Lake Forest, IL 60045 USA
Ketorolac Tromethamine Injection, USP is available for intravenous (IV) or intramuscular (IM) administration.

**DESCRIPTION**

Ketorolac tromethamine is an analgesic used for the management of moderate to severe pain. It is a nonsteroidal anti-inflammatory drug (NSAID) that belongs to the cyclooxygenase-2 (COX-2) inhibition class.

- **S-form** having analgesic activity.
- The activity of ketorolac tromethamine is associated with the S-form.

**Linear Kinetics**

In adults, following administration of single ORAL, IM or IV doses of ketorolac tromethamine in the pediatric population, the rate of metabolism and, therefore, the elimination half-life, is increased in the elderly individuals and in hepatically and renally impaired patients.

| Age Group | Mean Value (± SD) mcg/mL | % Variation from mean
|-----------|--------------------------|------------------------|
| Healthy Elderly Subjects | 4.5 ± 1.0 | -
| Healthy Young Subjects | 4.0 ± 0.5 | -

Table 2: The Influence of Age, Liver and Kidney Function, on the Clearance and Terminal Plasma Concentration of Ketorolac Tromethamine.

| Age Group | Mean Value (± SD) mcg/mL | % Variation from mean
|-----------|--------------------------|------------------------|
| Healthy Elderly Subjects | 4.5 ± 1.0 | -
| Healthy Young Subjects | 4.0 ± 0.5 | -

**WARNINGS**

Ketorolac tromethamine is contraindicated for the treatment of peri-operative pain in the setting of closed head trauma or other conditions that may compromise intracranial perfusion pressure.

- **Acute Pain in Adult Patients**
  - In a postoperative study, where all patients received morphine by a PCA device, patients treated with ketorolac tromethamine required significantly less morphine (26%) than the placebo group. Analgesia was maintained for up to 8 hours after the fourth dose.

**PRECAUTIONS**

- **Use of Other Drugs**
  - Concomitant use of ketorolac tromethamine with muscle relaxants has not been formally studied.
  - Ketorolac tromethamine is not recommended concurrently with aspirin or other salicylates.

**Pregnancy**

Ketorolac tromethamine has been reported to cause fetal harm when administered to pregnant women. It should not be used in pregnant women unless the potential benefits outweigh the potential risks.

**Nursing Mothers**

Exercise caution when ketorolac is administered to a nursing woman. Available information has not been sufficient to determine whether ketorolac is excreted in human milk.

**Adverse Reactions**

- **Gastrointestinal**
  - Anemia is sometimes seen in patients receiving NSAIDs, including ketorolac tromethamine. Anemia may cause symptoms such as fatigue, weakness, and shortness of breath.

**Drug Interactions**

- **Probenecid**
  - Use of ketorolac tromethamine with muscle relaxants has not been formally studied.

**Additional Precautions**

- **Long-term Administration**
  - Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury.

**Recommended Dose**

Ketorolac tromethamine injection has been used concomitantly with morphine and other commonly used analgesics. The dose should be individualized based on the patient's response and medical condition.

**Pharmacology**

- **Metabolism**
  - Ketorolac tromethamine is metabolized by the liver and excreted primarily in urine.
  - The mean value was simulated from observed plasma concentration data and standard deviation was simulated from percent coefficient of variation.