Ketorolac Tromethamine Injection, USP

15 mg per mL | NDC 70860-700-02
30 mg per mL | NDC 70860-701-03
60 mg per 2 mL | NDC 70860-701-04

ATHENEX AccuraSEE™ PACKAGING AND LABELING

BIG, BOLD AND BRIGHT — TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT

DIFFERENTIATION IN EVERY LABEL, DESIGNED TO HELP REDUCE MEDICATION ERRORS

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR KETOROLAC TROMETHAMINE INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION
# Ketorolac Tromethamine Injection, USP

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Glass Vial</th>
<th>NDC</th>
<th>Unit of Sale</th>
<th>Bar Coded</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mg per mL</td>
<td>Yes</td>
<td>70860-700-02</td>
<td>25 vials</td>
<td>Yes</td>
</tr>
<tr>
<td>30 mg per mL</td>
<td>Yes</td>
<td>70860-701-03</td>
<td>25 vials</td>
<td>Yes</td>
</tr>
<tr>
<td>60 mg per 2 mL</td>
<td>Yes</td>
<td>70860-701-04</td>
<td>25 vials</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

With a unique AccuraSEE label design for every Athenex product, we’re helping your pharmacy to reduce the risk of medication errors. The idea is simple: “So what you see is exactly what you get.”

To order, call 1-855-273-0154 or visit www.Athenexpharma.com

---

Athenex, AccuraSEE and all label designs are copyright of Athenex.

©2018 Athenex. APD-0023-01-3/18
KETOROLAC TROMETHAMINE Injection, USP

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.
- Therapy should always be initiated with IV or IM dosing of ketorolac tromethamine, and oral ketorolac tromethamine is to be used only as continuation treatment, if necessary.
- Patients should be switched to alternative analgesics as soon as possible, but ketorolac tromethamine therapy is not to exceed 5 days.

IMPORTANT SAFETY INFORMATION

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 treatment following IV or IM 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 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.

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 WARNINGS and PRECAUTIONS).

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

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.

DOSSAGE 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).

KETOROLAC TROMETHAMINE tablets, USP

CONTRAINDICATIONS
- Ketorolac tromethamine is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac tromethamine.
- 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.
- Ketorolac tromethamine should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.
- Ketorolac tromethamine is contraindicated as prophylactic analgesic before any major surgery.
- Ketorolac tromethamine is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- Ketorolac tromethamine is contraindicated in patients with advanced renal impairment or in patients at risk for renal failure due to volume depletion.
- Ketorolac tromethamine is contraindicated in labor and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine musculature, thus increasing the risk of uterine hemorrhage.
- Ketorolac tromethamine inhibits platelet function and is, therefore, contraindicated in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding.
- Ketorolac tromethamine is contraindicated in patients currently receiving aspirin or NSAIDs because of the cumulative risk of inducing serious NSAID-related adverse events.
- The concomitant use of ketorolac tromethamine and probenecid is contraindicated.
- The concomitant use of ketorolac tromethamine and pentoxifylline is contraindicated.
- Ketorolac tromethamine injection is contraindicated for neuraxial (epidural or intrathecal) administration due to its alcohol content.

WARNINGS
- 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 adults. Ketorolac tromethamine is not indicated for use in pediatric patients.
- Ketorolac tromethamine is contraindicated in patients with previously documented peptic ulcers and/or gastrointestinal (GI) bleeding.
- To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest possible duration.
CONTINUED...

- NSAIDs, including ketorolac tromethamine, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

- In late pregnancy, as with other NSAIDs, ketorolac tromethamine should be avoided because it may cause premature closure of the ductus arteriosus.

**PRECAUTIONS**

- Ketorolac tromethamine cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency.

- Ketorolac tromethamine should be used with caution in patients with impaired hepatic function or a history of liver disease. Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including ketorolac tromethamine.

- Anemia is sometimes seen in patients receiving NSAIDs, including ketorolac tromethamine. Patients receiving ketorolac tromethamine who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants, should be carefully monitored.

- Since cross-reactivity, including bronchospasm, between aspirin and other nonsteroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, ketorolac tromethamine should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with pre-existing asthma.

- Ketorolac tromethamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

- The use of ketorolac tromethamine is contraindicated in labor and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage.

- The use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive.

- Exercise caution when ketorolac is administered to a nursing woman.

- 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.

- Extreme caution and reduced dosages and careful clinical monitoring must be used when treating the elderly with ketorolac tromethamine.

**OVERDOSAGE**

- Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

- Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 g to 100 g in adult 1.5 g/kg to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large oral overdose (5 to 10 times the usual dose).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch.
Or call 1-800-FDA-1088.

Please see full prescribing information for KETOROLAC TROMETHAMINE Injection, USP.