

KETOROLAC TROMETHAMINE UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Non-narcotic analgesics - Non-steroidal anti-inflammatory drugs (NSAIDs)

BRAND NAME (Inactive): Toradol 10 mg oral tablets
(Generic) (ketorolac tromethamine)

FDA INDICATIONS:

Ketorolac is indicated for the short-term (5 days or less) management of moderately severe acute pain that requires analgesia at the opioid level. It is **NOT** indicated for minor or chronic painful conditions.

ICD-9 Code:

Various codes may apply; any ICD-9 code that states acute pain from any origin is acceptable.

QUANTITY LIMITATIONS (QL) CRITERIA:

- *QL: (short term only, not appropriate for extended-supply)*
Ketorolac 20 tablets/5 days supply within 30-day period (or 200 mg/30 days)
- *If a patient requires additional medication, please follow the criteria developed for Ketorolac.*

RATIONALE:

Quantity limitations are based on restrictions placed by the FDA in the package inserts for Ketorolac:

- Ketorolac tablets are only indicated as follow up to ketorolac injection: Combined use beyond 5 days increases the risk of serious adverse events such as peptic ulcer and gastrointestinal bleeding/perforation. The maximum dose of ketorolac tablets per day is 40 mg, or 4 tablets. Therefore, the maximum number of tablets per prescription should be 20 or less due to the fact that combined usage of injection and oral should not exceed 5 days.

CRITERIA FOR EXCEEDING QL:

1. Convey to physician the amount of the drug that the patient has already received (refer to QL) and ask if the patient needs more than that amount. **AND**
2. Ketorolac tablets are only indicated as follow up to ketorolac injection. **AND**
3. Patient must have the diagnosis of moderate to severe acute pain (not chronic, osteoarthritis, or rheumatoid arthritis). **AND**
4. Patient **May Not** have a history of any of the following
 - a. Previous (within previous year) or active GI bleed and/or perforation. **OR**
 - b. History or active peptic ulcer disease or presently taking one of the following medications:
 - Aciphex (rabeprazole)
 - Axid (nizatidine)
 - Carafate (sucralfate)
 - Nexium (esomeprazole)
 - Pepcid (famotidine)
 - Prevacid (lansoprazole)

- Prilosec (omeprazole)
 - Propulsid (cisapride)
 - Protonix (pantoprazole)
 - Tagamet (cimetidine)
 - Zantac (ranitidine) **OR**
- c. Previous documented allergic reaction to aspirin or any other NSAID (i.e., bronchospastic response, chronic urticaria, angioedema) **OR**
 - d. Kidney impairment is present with a serum creatinine of >1.2mg/dl. (documented serum creatinine within past year) **AND**
5. Prescribing physician must be aware that over 5 days is beyond FDA approved labeling.
 6. Unless this is the first request, medical records are required
 7. Alert physician that a pattern of inappropriate prescribing will be flagged and reviewed for potential quality of care issues.

- **Due to the high potential for serious adverse effects with the medication, additional quantities should not be authorized.**

BLACK BOX WARNINGS:

1. **Gastrointestinal effects: Ketorolac may cause peptic ulcers, GI bleeding and/or perforation.**
2. **Renal effects: Ketorolac is contraindicated in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion.**
3. **Risk of bleeding: Ketorolac 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.**
4. **Hypersensitivity: Reactions ranging from bronchospasm to anaphylactic shock have occurred. Ketorolac is contraindicated in patients with previously demonstrated allergic manifestations to aspirin and NSAIDs.**
5. **Labor, Delivery and Nursing: Ketorolac is contraindicated in labor and delivery due to inhibition of fetal circulation and inhibition of uterine contractions.**
6. **Concomitant use of NSAIDs: Ketorolac is contraindicated in patients currently receiving aspirin and/or NSAIDs because of cumulative risk of inducing serious NSAID-related side effects.**
7. **Ketorolac is contraindicated as prophylactic analgesic before major surgery and is contraindicated intraoperatively when hemostasis is critical because of increased risk of bleeding.**

RATIONALE:

This medication carries risk of serious adverse effects. Inappropriate use (such as dosing beyond label recommendations) will not provide better efficacy, but will result in increasing the risk of adverse events. Ketorolac has a narrow FDA labeling and utilization management criteria are intended to help prevent unnecessary adverse events.

NURSING ASSESSMENT:

1. Document indications for therapy & type, location, intensity, duration, and onset of symptoms.
2. Note previous experiences with Ketorolac or other NSAIDs and the results obtained.
3. Determine any underlying evidence of liver or renal dysfunction.

PROVIDER EDUCATION:

1. Recommend that it is not recommended to exceed prescribed dosage.
2. Caution this drug may cause drowsiness and dizziness. Other side effects that may be present include: vasodilation, pallor, excessive thirst, nausea, dyspepsia, flatulence, and GI fullness.
3. Avoid alcohol and all OTC agents without the approval of your physician.

4. Dosage should be adjusted for patients 65 years of age and older, for patients less than 50kg (110 lbs), and for patients with moderately elevated serum creatinine.
5. Inform patient of potential risk.

CLINICAL OUTCOME:

Effective control for moderately severe acute pain that requires analgesia at the opioid level

ADDITIONAL INFORMATION:

Dose of Ketorolac is not to exceed 5 days, because of increased risk of adverse events. Oral Ketorolac is indicated only as a continuation therapy to IV/IM, and the combined duration of use of oral and IV/IM is not to exceed 5 days. The recommended total daily oral dose of Ketorolac is 40 mg maximum.

RISK FACTORS/CONTRAINDICATIONS:

- Ketorolac is contraindicated in patients currently receiving aspirin and/or NSAIDs because of cumulative risk of inducing serious NSAID-related side effects.
- Please see Black Box Warnings for additional precautions.

Initial Date: January 1999

Review Date: 9/2008

REFERENCES:

1. Toradol (ketorolac tromethamine) product information. Roche Laboratories, Nutley, NJ. 2002.
2. Physician's Desk Reference, Nurse's Handbook, 3rd edition 1998.
3. AMA Drug Evaluations, 1995.
4. Saunders' Nursing Drug Handbook; W.B. SaundersCo.,1999.
5. PDR Nurse's handbook; 3rd edition. 1998