Kelorac

Ketorolac Tromethamine USP

Composition

Kelorac Tablet: Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.
Kelorac 30 IV/IM injection: Each 1 ml ampoule contains Ketorolac Tromethamine USP 30 mg.

Pharmacology

Kelorac (Ketorolac Tromethamine) is a member of pyrrolopyrrole group of nonsteroidal anti-inflammatory drug (NSAID) that exhibits analgesic, anti inflammatory and antipyretic activity. It has more pronounced analgesic activity than most NSAIDs. It inhibits synthesis of prostaglandin and is a peripherally acting analgesic.

Indication

- Short term management of moderate postoperative pain and acute & chronic musculoskeletal pain as a continuation of treatment.
- Short-term management of moderate to severe acute post-operative pain.

Dose & Administration

a) Route of administration: Oral
Dose range: 10 mg tablet 4-6 hourly, elderly: 6-8 hourly. Maximum dose is 40 mg daily.
b) Route of administration: Parenteral
Adult patients (<65 years): Ketorolac Tromethamine is for administration by intramuscular or intravenous injection. Initial dose is 60 mg IM or 30 mg IV. Maintenance dose is 30 mg IM/IV 6 hourly. Maximum dose is 120 mg/day,
For elderly patients (>65 years), patients with renal impairment & those weighing less than 50 kg, the initial dose is 30 mg IM. Maintenance dose is 10-15 mg IM/IV 6 hourly. Maximum dose is 60 mg/day. Maximum duration of treatment should not exceed 2 days or as directed by the physician.

Contra-indication

Ketorolac Tromethamine is contraindicated against patient with a history of peptic ulcer or gastro intestinal bleeding, cerebrovascular bleeding, coagulation disorder, renal impairment, asthma and patient with hypersensitivity to Ketorolac Tromethamine.

Warning and Precaution

The total combined duration of use of Ketorolac Tromethamine tablet and IV/IM dosing should not exceed 5 days in adults. For the short-term management of pain (other than postoperative) Ketorolac Tromethamine injection is not recommended for longer use (more than 5 days) because of the possibility of increase frequency and severity of adverse events, Ketorolac Tromethamine tablet is not recommended for use beyond 7 days and is not recommended for chronic use. Patient with liver dysfunction the administration of Ketorolac Tromethamine should be discontinued. High oral dose (e.g. 80 or 120 mg/day) are not recommended as risk of serious gastrointestinal toxicity such as ulceration and stomach perforation can occur when used with NSAIDs.

Side-effects

a) Common: Ketorolac Tromethamine is generally well tolerated, however side effects include dry mouth, nausea, vomiting, diarrhea, peptic ulcer, dizziness, sweating, convulsion, reaction, myalgia may be occurred.
b) Rare: Visible water retention, an infection, high levels of potassium in the blood, high Blood Pressure, stomatitis, a condition with painful swelling and sores inside the mouth, inflammation of the skin due to an allergy, a skin rash.

Use in Pregnancy & Lactation

This medication should be used only when clearly needed during the first 6 months of pregnancy. It is not recommended for use during the last 3 months of pregnancy, This drug passes into breast milk. Therefore, breast feeding while using this drug is not recommended.

Use in Children & Adolescents

Safety and efficacy in children have not been established. Therefore Ketorolac Tromethamine is contraindicated for use in children under 16 years of age.

Drug Interaction

a) With medicine: Ketorolac Tromethamine should not be used with the following medications because very serious interactions may occur such as high doses of aspirin, cidofovir, other NSAIDs (eg. ibuprofen, naproxen), probenecid.
b) With food & other: Taking ketorolac with a high-fat breakfast slows the speed of drug absorption by about an hour, but it does not affect overall blood levels of the drug. To lessen stomach upset, ketorolac tablets should be taken with a meal or a snack.

Overdose

Symptoms of overdose may include severe stomach pain, vomiting extreme drowsiness, slow/shallow breathing and loss of consciousness.

Storage

Store below 30° C. Protect from light and moisture. Keep all medicines out of reach of children.

Packing

Kelorac: Each box contains 30 (3 X 10's) tablets in blister pack.
Kelorac 30 IV/M injection: Each box contains 5 (1 x 5's) ampoules of 1 ml in blister pack.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh

Kelorac Injection is Manufactured by
Apex Pharma Ltd.
Shafipur, Kaliakair, Gazipur, Bangladesh.
for **ONE PHARMA LTD.**

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