Etolac
Ketorolac

Composition:
Etolac Tablet: Each tablet contains Ketorolac Tromethamine USP 10 mg.
Etolac Injection: Each ampoule contains Ketorolac Tromethamine USP 10 mg.
Etolac 30 Injection: Each ampoule contains Ketorolac Tromethamine USP 30 mg.
Etolac 60 Injection: Each ampoule contains Ketorolac Tromethamine USP 60 mg.

Description:
Etolac contains Ketorolac Tromethamine which is a member of the pyrrolopyrrole group of non-steroidal anti-inflammatory drug (NSAID) that exhibits analgesic, anti-inflammatory and antipyretic activity. It inhibits the cyclo-oxygenase enzyme system and hence prostaglandin synthesis. It has more pronounced analgesic activity than most NSAIDs.

Indication:
Etolac is indicated in short-term management of moderate to severe pain such as acute pain,
renal colic, cancer pain, postoperative pain, traumatic pain, musculoskeletal pain and dental pain.

Dosage and Administration:

Dosage should be adjusted according to the severity of the pain and the response of the patient. The lowest effective dose should be used for the shortest possible time in all patient populations.

For injection dosage form:
Etolac ampoules are for administration by intramuscular or bolus intravenous injection. Bolus intravenus doses should be given over no less than 15 seconds. The IM administration should be given slowly and deeply into the muscle. *Adults (Under 65 years)*

The usual recommended initial dose is 10 mg to 30 mg, followed by 10 mg to 30 mg at 4 to 6 hourly intervals, up to a maximum daily dose of 90 mg. In the ini t ial postoperat ive period. Etolac may be given as often as every 2 hours if needed. Single-dose treatment: IM 60 mg or IV 30 mg. *Elderly (65 years and older), Renally impaired patients and patients less than 50 kg* An initial dose of 10 mg to 15 mg, followed by 10 mg to 15 mg at 4 to 6 hourly intervals, up to a maximum daily dose of 60 mg. Single-dose treatment: IM 30 mg or IV 15 mg. Etolac is contraindicated in patients with more severe renal impairment. The maximum duration of treatment is 2 days. *Paediatric Patients (2 to 16 years) : The paediatric population should receive only a single dose or Etolac*

injection.
IM dosing : One dose of 1 mg/kg body weight up to a maximum of 30 mg.
IV dosing: One dose of 0.5 mg/kg body weight up to a maximum of 15 mg.

For oral dosage form
Adults(Under 65 years)

The usual oral dose of Etolac is 10 mg every 4 to 6 hours for pain as required. Doses exceeding 40 mg per day are not recommended. Elderly (65 years and older) The usual oral dose of Etolac is 10 mg every 6 to 8 hours. Daily doses of 30 mg to 40 mg per day should not be exceeded. The maximum duration of treatment is 7 days.

Transition From injectable to oral
For patients receiving Etolac Injection, and who are converted to Etolace Tablet, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, renally-impaired patients and patients less than 50 kg) and the oral component should not exceed 40 mg on the day, the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

In adults, the maximum combined duration of use (parenteral and oral Etolac) is limited to 5 days.

Side effect
Cardiovascular/haematological: Flushing, bradycardia, pallor, purpura, thrombocytopenia, hypertension, inhibition of platelet aggregation & prolonged bleeding time, postoperative wound haemorrhage and haematoma. Dermatological : Rash or pruritus. Less frequently, Lyell's syndrome, StevensJohnson syndrome, maculo-papular rash, exfoliative dermatitis, or urticaria.

Gastrointestinal : Nausea, dyspepsia, GI pain, constipation, diarrhea, flatulence, gastrointestinal fullness, vomiting or stomatitis. Less frequently, peptic ulceration, gastrointestinal hemorrhage, gastrointestinal perforation, melena, rectal bleeding, gastritis, eructation, anorexia, or increased appetite. Very rarely, pancreatitis.

Neurological: Drowsiness, dizziness, headache, sweating, injection site pain. Less frequently convulsions, vertigo, tremors, abnormal dreams, hallucinations, or euphoria. Very rarely, paresthesia, depression, insomnia, inability to concentrate nervousness, excessive thirst, dry mouth, abnormal thinking, hyperkinesis, or stupor.

Respiratory: Less frequently, dyspnea, asthma and pulmonery edema. Very rarely, rhinitis or cough.

Renal: Increased urinary frequency, oliguria, acute renal failure, hyponatraemia, hyperkalaemia, haemolytic uraemic syndrome, flank pain (with or without haematuria), raised serum urea, creatinine and urinary symptoms & acute renal failure.

Other: Edema. Less frequently, hypersensitivity reactions (such as anaphylaxis, bronchospasm, laryngeal edema, tongue edema, hypotension), flushing, weight gain, or fever. Very rarely asthenia.

Overdose:

In controlled overdosage, daily doses of 360 mg of Ketorolac given for 5 days (three times the highest recommended dose), caused abdominal pain and peptic ulcers which healed after discontinuation of dosing. Metabolic acidosis has been reported following intentional overdosage. Single overdoses of Ketorolac have been variously associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers and/or erosive gastritis and renal dysfunction which have resolved after discontinuation of dosing.

Dialysis does not significantly clear Ketorolac Tromethamine from the blood stream. Patients shouldbe managed by symptomatic and supportive care following a NSAIDs overdose. There are no specific antidotes. Emesis and/or act ivated charcoal (60 g to 100 g in adul ts, 1 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).

Contraindication

- Moderate or severe renal impairment (serum creatinine> 180 micromol/L).
- A history of haemorrhagic diatheses, including coagulation disorders.
- Patients on full anticoagulation therapy.
- Patients who have had operations with a high risk of haemorrhage or incomplete haemostasis.
- A hypersensitivity to Ketorolac Tromethamine or other NSAIDs and those patients In whom aspirin or other prostaglandin synthetase inhibitors induce allergic reactions.
- Individuals with the complete or partial syndrome of nasal polyps, angioedema or bronchospasm.
- A history of asthma.
- Patients with a prior history of Stevens-Johnson syndrome or vesicular bullous rash.
- Suspected or confirmed cerebrovascular (intracranial) bleeding.- A history of gastrointestinal ulcer and/or bleeding.
- Prophylactic administration before major surgery or intraoperatively when haemoetasis is critical because of the increased risk of bleeding.

Pregnancy and lactation:

It is detected in human milk. Safety in pregnancy has not been established. It is not recommended during pregnancy, labour or delivery and in mothers who are breast-feeding.

Drug Interaction:

Ketorolac Tromethamine should not be used with other NSAIDs or in patients receiving aspirin because of the potential for additive side-effects. Care should be taken when administering Ketorolac Tromethamine with anticoagulants since co-administration may cause an enhanced anticoagulant effect. Ketorolac Tromethamine and other NSAIDs can reduce the anti-hypertensive effect of beta-blockers and may increase the risk of renal impairment when administered concurrently, since. some prostaglandin synthesis inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possibly enhance its toxicity. Probenecid should not be administered concurrently with Ketorolac Tromethamine because of increases in Ketorolac plasma level and half-life.

Precaution:

It should be noted that when administered intravenously through the same IV catheter as Morphine the two drugs have been known to sometimes combine to form a precipitate in the IV, which may block the line. Ketorolac is not recommended for pro-operative analgesia or coadministration with anesthesia because it inhibits platelet aggregation. Ketorolac Is not recommended for obstetric analgesia because it has not been adequately tested for obstetrical administration and has' demonstrable fetal toxicity in laboratory animals. Ketorolac is not recommended for long-term chronic pain patients.

Pharmaceutical precaution

It is detected in human milk. Safety in pregnancy has not been established. It is not recommended during pregnancy, labour or delivery and in mothers who are breast-feeding.

Presentation

Elotac Tablet : Each box contains 2 x 10's tablet in Alu-Alu blister strip.
Etolac Injection : Each box contains 2 x 5's ampoules.
Etolac 30 Injection : Each box contains 2 x 5's ampoules.
Etolac 60 Injection : Each box contains 1 ampoules.

IBN SINA

Manufactured by:
The **IBN SINA** Pharmaceutical Industry Ltd.
Shafipur, kaliakoir, Gazipur, Bangladesh.