

Toralin

Ketorolac Tromethamine USP

COMPOSITION

Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.

PHARMACOLOGY

Toralin (Ketorolac Tromethamine) is a potent analgesic of the non-steroidal anti-inflammatory drugs (NSAIDs). It acts by inhibiting the cyclo-oxygenase enzyme system and hence inhibits the prostaglandin synthesis. It demonstrates a minimal anti-inflammatory effect at its analgesic dose.

INDICATIONS

It is indicated for the short-term management of moderate to severe acute post-operative pain.

DOSAGE AND ADMINISTRATION

Recommended dose is 10 mg every 4-6 hours. It should be used short-term only (up to 7 days) and are not recommended for chronic use. Doses exceeding 40 mg/day is not recommended.

CONTRAINDICATIONS

Toralin is contraindicated in patients having hypersensitivity to this drug or other NSAIDs. It should not be used in children under 16 years of age. It is also contraindicated as prophylactic analgesic before surgery.

WARNING AND PRECAUTION

Caution should be exercised in patients over the age of 65 years. Caution should also be taken in patients with active or suspected peptic ulcer or gastrointestinal bleeding or asthma and liver dysfunction.

SIDE EFFECTS

Commonly occurring side effects are nausea, vomiting, gastro-intestinal bleeding, melana, peptic ulcer, pancreatitis, anxiety, drowsiness, headache, excessive thirst, fatigue, bradycardia, hypertension, palpitation, chest pain, infertility in female and pulmonary edema.

USE IN PREGNANCY AND LACTATION

US FDA Pregnancy category of Ketorolac Tromethamine is C. So, Ketorolac Tromethamine should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the fetus.

USE IN CHILDREN AND ADOLESCENTS

Limited information is available regarding the pharmacokinetics of dosing of Ketorolac Tromethamine in the paediatric population.

DRUG INTERACTIONS

Other NSAIDs or Aspirin: Increase the side effects of Ketorolac Tromethamine.

Anti-coagulants: Enhance anti-coagulant effect.

Beta Blocker: Reduce the anti-hypertensive effect .

ACE Inhibitors: Increase the risk of renal impairment.

Methotrexate: Enhance the toxicity of methotrexate.

OVERDOSAGE

Single overdoses of Ketorolac Tromethamine have been associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers, erosive gastritis and renal dysfunction which have resolved after discontinuation of dosing.

Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.

STORAGE

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

HOW SUPPLIED

Each box contains 30 tablets in Alu-PVDC blister pack.