Temoket®

Ketorolac

COMPOSITION:

Temoket® 10 Tablet: Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.

Temoket® 30 Injection: Each 1 ml ampoule contains Ketorolac Tromethamine USP 30 mg.

PHARMACOLOGY:

Ketorolac Tromethamine is strong analgesic drug (pain killer). It belongs to group of Non Steroidal Anti-inflammatory Drugs (NSAIDs). Ketorolac Tromethamine is a heterocyclic acetic acid derivative. Like other NSAIDs, it decreases prostaglandin synthesis by non-selective competitive inhibition of cyclo-oxygenase (COX-I and COX-II), producing peripherally-medicated analgesia.

INDICATION:

Temoket ® (Ketorolac) is indicated for the short term management of moderate to severe acute pain, Post operative pain, Cancer pain, Pain of renal colic, Dental pain and ocular inflammation.

DOSE & ADMINISTRATION:

Temoket ® Injection multiple-Dose Treatment (IV or IM): Patients <65 years of age: The recommended dose is 30 mg Temoket injection every 6 hours. The maximum daily dose should not exceed 120 mg. Patients >65 years of age, renally impaired patients , and patients less than 50 kg : The recommended dose is 15 mg Temoket ® injection every 6 hours. The maximum daily dose for these populations should not exceed 60 mg. For breakthrough pain, do not increase the dose or the frequency of Ketorolac Tromethamine.

CONTRA-INDICATION:

Ketorolac Tromethamine is contraindicated in patients having Peptic ulcers, Bleeding disorders, Hypersensitivity, Nasal polyps, Asthma.

WARNING AND PRECAUTION:

When administering Temoket ® injection, the IV bolus must be given over no less than 15 seconds. The IM administration should be given slowly and deeply into the muscle. Patients over the age of 65 years may be at a greater risk of experiencing adverse events than younger patients. Should be used cautiously above 65 years old, in kidney insufficiency, Liver patients. Avoid using the drug in children. Avoid using the drug to pregnant and lactating women.

SIDE EFFECTS:

Commonly occurring side effects are Nausea, Vomiting, Gastrointestinal bleeding, Peptic ulcer, Pancreatitis, Anxiety, Drowsiness, Headache, Thirst, Malaise, Fatigue, Pruritis, Flushing bradycardia, Hypertension, Palpitation, Chest pain, Asthma and Pulmonary edema.

USE IN PREGNANCY & LACTATION:

Pregnancy category C. Safety in human pregnancy has not been established. Ketorolac Tromethamine has been detected in human milk at low levels. Ketorolac tromethamine is therefore contraindicated during pregnancy, labor or delivery or to mothers who are breast feeding.

USE IN CHILDREN & ADOLESCENTS:

Data has not been established for use in children less than 2 years old.

Pediatric Patients (2 to 16 years of age): IM Dosing: One dose of 1 mg/kg up to a maximum of 30 mg.

IV Dosing: One dose of 0.5 mg/kg up to a maximum of 15 mg.

DRUG INTERACTION:

Care should be taken when administering Ketorolac Tromethamine with anticoagulants since co-administration may cause an enhanced anticoagulant effect. Caution is advised when methotrexate is administered concurrently. Probenecid should not be administered concurrently with Ketorolac Tromethamine because of increasing in plasma level and half life.

OVERDOSE:

In controlled over dosage, daily doses of 360 mg of Ketorolac Tromethamine IV/IM given for five days (3 times the highest recommended dose), caused abdominal pain and peptic ulcer which healed after discontinuation of dosing. Metabolic acidosis reported following intentional over dosage.

STORAGE:

Store in a dry and cool place below 25^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Temoket ® 10 Tablet: Each box contains 3x10's tablets in Alu-Alu blister pack.

Temoket ® 30 Injection: Each box contains 1's 1 ml Ampoule with a sterile disposable syringe.

Manufactured by
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Team Pharmaceuticals Ltd.
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