

# Roket

(Ketorolac Tromethamine USP)

## PRESENTATION :

**Roket 10 Tablet :** Each film-coated tablet contains Ketorolac Tromethamine USP 10 mg.

**Roket 30 Injection :** Each ml injection contains Ketorolac Tromethamine USP 30 mg.

**Roket 60 Injection :** Each 2 ml injection contains Ketorolac Tromethamine USP 60 mg.

## INDICATIONS :

Roket (Ketorolac) is indicated for the short term management of moderate to severe acute pain, postoperative pain, cancer pain, pain of renal colic, dental pain and ocular inflammation.

## Dosage & Administration :

**Injection :** For adult patients (<65 years) : Initial dose is 60 mg IM (single) or 30 mg IV (single). Maintenance dose is 30 mg IM/IV 6 hourly. Maximum dose is 120 mg/day. For elderly patients (>65 years) : Initial dose is 30 mg IM. Maintenance dose is 10-15 mg IM/IV 6 hourly. Maximum dose is 60 mg/day. The duration of treatment should not exceed two days.

**Tablet :** 10 mg every 4-6 hourly. The maximum doses are 40 mg per day. For patients receiving Ketorolac Tromethamine injection and are converted to oral tablet, the total combined daily dose should not exceed 90 mg (60 mg for elderly, renal 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.

## SIDE EFFECTS :

Commonly occurring side effects are nausea, vomiting, gastrointestinal bleeding, peptic ulcer, pancreatitis, anxiety, drowsiness, headache, thirst, malaise, fatigue, pruritus, flushing, bradycardia, hypertension, palpitation, chest pain, asthma, pulmonary edema etc.

## CONTRAINDICATIONS :

Ketorolac Tromethamine is contraindicated in patients having hypersensitivity to this drug or other NSAIDs, asthma, active peptic ulceration, moderate to severe renal impairment (serum creatinine > 160 micromol/l). Ketorolac Tromethamine is contraindicated as prophylactic analgesia before surgery due to inhibition of platelet aggregation and is contraindicated intraoperatively because of increased risk of bleeding.

## Drug Interactions :

Care should be taken when administering Ketorolac Tromethamine with anticoagulants since co-administration may cause an enhanced anticoagulant effect. Ketorolac Tromethamine and other non-steroidal anti-inflammatory drugs can reduce the antihypertensive effect of beta-blockers and may increase the risk of renal impairment when administered concurrently with ACE inhibitors, particularly in volume depleted patients. Caution is advised when methotrexate is administered concurrently, since some prostaglandin synthesis inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possible enhance its toxicity. Probenecid should not be administered concurrently with Ketorolac Tromethamine because of increasing in Ketorolac Plasma level and half-life.

## PRECAUTIONS :

Patients over the age 65 years may be at a greater risk of experiencing adverse events than younger patients. Ketorolac Tromethamine can cause gastrointestinal irritation, ulcers or bleeding in patients with or without a history of previous symptoms. Bronchospasm may be precipitated in patients with a history of asthma. Since Ketorolac Tromethamine and its metabolites are excreted primarily by kidney, patients with moderate to severe impairment of renal function (serum creatinine greater than 160 micromol/l) should not receive. Fluid retention and oedema have been reported with the use of Ketorolac Tromethamine.

## USE IN PREGNANCY & LACTATION :

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, labour or delivery, or to mothers who are breast feeding.

## PHARMACEUTICAL PRECAUTIONS :

Store in a cool and dry place, away from light.

## PACKAGING :

**Roket 10 Tablet :** Each box contains 2 x 10 tablets in blister strips.

**Roket 30 Injection :** Each box contains 1 ampoule in blister strip with a sterile 3 ml disposable syringe.

**Roket 60 Injection :** Each box contains 1 ampoule in blister strip with a sterile 3 ml disposable syringe.

Manufactured by :

**GLOBE PHARMACEUTICALS LTD.**  
**BANGLADESH.**

