

# OFFPAIN Injection

## Ketorolac Tromethamine USP

### Composition:

**Ofpain-30** Injection: Each 1 ml ampoule contains Ketorolac Tromethamine USP 30 mg.

**Ofpain-60** Injection: Each 2 ml ampoule contains Ketorolac Tromethamine USP 60 mg.

### Pharmacology :

**Ofpain** is a member of the pyrrolo-pyrrole group of the non-steroidal anti-inflammatory drugs (NSAIDs). It inhibits the cyclo-oxygenase enzyme system and hence prostaglandin synthesis. **Ofpain** is not an anesthetic agent and possesses no sedative or anxiolytic properties; therefore it is not recommended as a preoperative medication for the support of anesthesia when these effects are required. It is not an opioid and has no known effects on opioid receptors.

### Indication:

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

### Dosage & Administration:

*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 60 mg/day.

The total duration of **Ofpain** Injection administration should not exceed 5 days because adverse effects may increase with prolonged usage.

### Side-effects:

Commonly occurring side-effects are nausea, vomiting, gastro-intestinal bleeding, melaena, peptic ulcer, pancreatitis, anxiety, drowsiness, dizziness, headache, hallucination, excessive thirst, inability to concentrate, insomnia, malaise, fatigue, pruritus, urticaria, skin photosensitivity, Lyell's syndrome, Stevens-Johnson syndrome, flushing, bradycardia, hypertension, palpitation, chest pain, infertility in female, dyspnoea, asthma, pulmonary oedema, fever & pain at injection site.

### Contraindication:

**Ofpain** injection is contraindicated in patients having hypersensitivity to ketorolac tromethamine or other NSAIDs, aspirin or other prostaglandin synthesis inhibitor-induced allergic reactions. It is also contraindicated in a history of peptic ulcer or gastro-intestinal bleeding, moderate or severe renal impairment (serum creatinine >160 micromol/l), a history of asthma & children under 16 years of age. Ketorolac tromethamine is contraindicated as prophylactic analgesia before surgery due to inhibition of platelet

aggregation and is contraindicated intra-operatively because of increased risk of bleeding. It is also contraindicated during pregnancy, labor, delivery or lactation.

### Drug Interaction:

Ketorolac tromethamine should not be used with other NASIDs or in patients receiving aspirin because of the potential for additive side-effects. Care should be taken when administering Ketorolac tromethamine with anti-coagulants since co-administration may cause an enhanced anti-coagulant 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 possibly enhance its toxicity. Probenecid should not be administered concurrently with ketorolac tromethamine because of increases in ketorolac plasma level and half-life.

### Precaution:

Patients over the age of 65 years may be at greater risk of experiencing adverse events than younger patients. **Ofpain** can cause gastro-intestinal 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 the kidney, patients with moderate to severe impairment of renal function (serum creatinine greater than 160 micromol/l) should not receive **Ofpain**. Fluid retention and oedema have been reported with the use of ketorolac tromethamine.

### Use in pregnancy & Lactation:

Safety in pregnancy has not been established. Ketorolac has been detected in human milk at low levels. **Ofpain** is therefore contraindicated during pregnancy, labor or delivery or in lactating mothers.

### Storage:

**Ofpain** injection should be stored in a cool & dry place, protected from light & moisture.

### How Supplied:

**Ofpain-30** Injection: Box containing 1 ml x 1 ampoule in blister pack.

**Ofpain-60** Injection: Box containing 2 ml x 1 ampoule in blister pack.

Manufactured by :



**KEMIKO PHARMACEUTICALS LTD.**

Bangladesh