

Repopain™

Ketorolac Tromethamine

PRESENTATION:

Repopain™ Tablet: Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.

INDICATION:

Repopain™ (Ketorolac Tromethamine) tablets are indicated for the short-term management of moderate to severe acute postoperative pain.

DOSAGE & ADMINISTRATION:

Repopain™ (Ketorolac Tromethamine) tablets are recommended for short-term use only (up to 7 days) and are not recommended for chronic use.

Adults: 10 mg every 4 to 6 hours as required. Doses exceeding 40 mg per day are not recommended. Opioid analgesics are required for optimal analgesic effect in the early postoperative period when pain is most severe. Ketorolac does not interfere with opioid binding and does not exacerbate opioid-related respiratory depression or sedation. For patients receiving parenteral Ketorolac Tromethamine and who are converted to Ketorolac Tromethamine oral tablets, the total combined daily dose should not exceed 90 mg (60 mg for 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.

Elderly: A longer dosing interval, e.g. 6-8 hourly, is advisable in the elderly. The lower end of the dosage range is recommended for patients over 65 years of age.

Children: Ketorolac Tromethamine is not recommended for use in children under 16 years of age.

CONTRAINDICATIONS & PRECAUTIONS:

- A history of peptic ulcer or gastro-intestinal bleeding.
- Suspected or confirmed cerebrovascular bleeding.
- Haemorrhagic diathesis, including coagulation disorders.
- Hypersensitivity to Ketorolac Tromethamine or other NSAIDs.
- The complete or partial syndrome of nasal polyps, angioedema or bronchospasm.
- Concurrent treatment with other NSAIDs, Oxpentifyline, Probenecid or Lithium salts.
- Moderate or severe renal impairment (serum creatinine > 160 micromole/L).
- A history of asthma.
- Ketorolac Tromethamine is contraindicated intraoperatively because of the increased risk of bleeding.
- Ketorolac Tromethamine is contraindicated in patients currently receiving Aspirin.

USE IN PREGNANCY & LACTATION:

Safety in human pregnancy has not been established. Ketorolac has been detected in human milk at low level. Ketorolac is therefore contraindicated during pregnancy, labour or delivery or in mothers who are breast feeding.

SIDE EFFECTS:

The following side effects have been reported with Ketorolac Tromethamine:

Nausea, dyspepsia, gastro-intestinal pain, gastro-intestinal bleeding, abdominal discomfort, diarrhea, constipation, flatulence, anxiety, drowsiness, headache, sweating, dry mouth, pruritus, urticaria etc.

DRUG INTERACTIONS:

Warfarin, Digoxin, Heparin and Salicylate should be used carefully with Ketorolac Tromethamine.

STORAGE:

Store in a cool & dry place, protected from light. Keep out of reach of children.

PACKING:

Repopain™ Tablet: Each box contains 3 x 10 tablets in blister strip.

Manufactured by:

Organic Health Care Ltd.

Gazipur, Bangladesh.

