

# Repopain™ 30 Injection

Ketorolac Tromethamine USP 30 mg

## PRESENTATION:

**Repopain™ 30 IV/IM Injection:** Each ml injection contains Ketorolac Tromethamine USP 30 mg.

## INDICATION:

Ketorolac Tromethamine is indicated for the short term management of moderate to severe acute postoperative pain.

## DOSAGE & ADMINISTRATION:

Repopain™ 30 Injection may be used as a single or multiple doses, on a regular or when necessary schedule for the management of moderately severe, acute pain that requires analgesia at the opioid level, usually in a postoperative setting. When administering Repopain™ 30 injection, the IV administration must be given over not less than 15 seconds. The IM administration should be given slowly and deeply into the muscle. The analgesic effect begins in 30 minutes with maximum effect in 1 to 2 hours after dosing IV or IM. Duration of analgesic effect is usually 4 to 6 hours.

**Single-Dose Treatment: The following regimen should be limited to single administration use only.**

### Adult Patients:

*IM Dosing:* Patients ≤ 65 years of age: One dose of 60 mg. Patients > 65 years of age, renally impaired and/or less the 50 kg of body weight: One dose of 30 mg.

*IV Dosing:* Patients ≤ 65 years of age: One dose of 30 mg. Patients > 65 years of age, renally impaired and/or less the 50 kg of body weight: One dose of 15 mg.

### 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.

### Multiple-Dose Treatment (IV or IM):

Patients <65 years of age: The recommended dose is 30 mg Ketorolac 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 Ketorolac 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.

## 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™ 30 IV/IM Injection:** Each box contains 1 ampoule of Ketorolac Tromethamine USP 30 mg/ml for IV/IM Injection.

**Repopain™ 30 IV/IM Injection:** Each box contains 5 ampoules of Ketorolac Tromethamine USP 30 mg/ml for IV/IM Injection.

Manufactured by:  
Apex Pharma Ltd. for

**Organic Health Care Ltd.**

