

Composition:

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

Keteks™ 30 IM/IV Injection: Each 1 ml ampoule contains Ketorolac Tromethamine USP 30 mg.

Keteks™ 60 IM/IV Injection: Each 2 ml ampoule contains Ketorolac Tromethamine USP 60 mg.

Description:

Keteks[™] (Ketorolac) is one of the most potent non-steroidal anti-inflammatory drugs (NSAIDs) yet introduced. It works by blocking the action of cyclo-oxygenase enzyme system, which is involved in the production of prostaglandins. Prostaglandins are produced in response to injury or certain diseases and would cause pain, swelling and inflammation. It may be a useful alternative to the use of opioids.

Indications:

Keteks[™] is indicated for the short-term management of moderate to severe acute post-operative pain.

Dosage & Administration:

Adult and child over 16 years: By mouth, 10 mg every 4-6 hours (elderly every 6-8 hours); max. 40 mg daily; max. duration of treatment 7 days.

By intramuscular injection *or* by intravenous injection over at least 15 seconds, initially 10 mg, then 10-30 mg every 4-6 hours as required (up to every 2 hours during initial postoperative period); max. 90 mg daily (elderly and patients weighing less than 50 kg max. 60 mg daily); max. duration of treatment 2 days.

When converting from parenteral to oral administration, total combined dose on the day of converting should not exceed 90 mg (60 mg in the elderly and patients weighing less than 50 kg) of which the oral component should not exceed 40 mg; patients should be converted to oral route as soon as possible.

Children: Not recommended under 16 years of age.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Gastrointestinal discomfort, nausea, diarrhea, ulceration, hypersensitivity reactions, rashes, headache, dizziness,

nervousness, depression, drowsiness, insomnia, vertigo, anaphylaxis, dry mouth, excessive thirst, psychotic reactions, convulsion, myalgia, hyperkalaemia, bradycardia, hypertension, palpitations, chest pain, post operative wound haemorrhage, etc. may occur.

Precautions:

Ketorolac should be used with caution in heart failure, hepatic impairment and conditions leading to reduction in blood volume or in renal blood flow. The dose of Ketorolac should be reduced in the elderly and in patients weighing less than 50 kg. It is recommended that patients with mild renal impairment should receive a reduced dose of Ketorolac and undergo close monitoring of renal function.

Use in Pregnancy & Lactation:

Pregnancy: Ketorolac is contraindicated during pregnancy, labour & delivery. **Lactation:** Ketorolac should be avoided during lactation period.

Contraindications:

Ketorolac Tromethamine is contraindicated in patients with known hypersensitivity to this drug or other NSAIDs, history of asthma, complete or partial syndrome of nasal polyps, bronchospasm, history of peptic ulceration or gastrointestinal bleeding, haemorrhagic diatheses (including coagulation disorders) and operations with high risk of haemorrhage or incomplete haemostasis, confirmed or suspected cerebrovascular bleeding, moderate or severe renal impairment, dehydration, pregnancy (including labor and delivery) and breast-feeding.

Storage Condition:

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

Presentation:

Keteks[™] **10** mg Tablet: Each box contains 3x10's tablets in blister pack.

Keteks[™] 30 IM/IV Injection: Each box contains 5 cartons; each of which contains 1 ampoule in blister pack & 1 disposable syringe.

Keteks™ 60 IM/ĪV Injection: Each box contains 1 ampoule in blister pack with a disposable syringe.

Keteks[™] Tablet

Manufactured by: Julphar Bangladesh Ltd. Sreepur, Gazipur, Bangladesh. Keteks[™] IV/IM Injection Manufactured by: Popular Pharmaceuticals Ltd. for Julphar Bangladesh Ltd. Sreepur, Gazipur, Bangladesh.