Eurolac®

Ketorolac Tromethamine

Composition:
Eurolac® tablet: Each tablet contains Ketorolac Tromethamine USP 10 mg .
Eurolac® 30 IV/IM injection: Each 1 ml ampoule contains sterile solution of Ketorolac Tromethamine USP 30 mg.
Eurolac® 60 IM injection: Each 2 ml ampoule contains sterile solution of Ketorolac Tromethamine USP 60 mg.

Description:
Eurolac® (Ketorolac Tromethamine) is a potent analgesic agent of the non-steroidal anti-inflammatory drug (NSAID's) with anti-inflammatory and antipyretic properties. It inhibits synthesis of prostaglandin and may be considered as a peripherally acting analgesic. **Eurolac®** is not an anesthetic agent and possesses no sedative or anxiolytic properties. Ketorolac Tromethamine is a non-narcotic analgesic.

Indication:
Eurolac® is indicated for the management of moderate to severe acute pain (usually in a severe acute post-operative pain).

Dosage and administration :
Oral: Adult : The recommended oral dose of Eurolac is 10 mg every 4-6 hours (elderly every 6 8 hours) daily for pain as required. **Eurolac®** tablet is recommended for short - term use only (up to 7 days) and are not recommended for chronic use.

Special doses instructions:
Oral: Patients > 65 years of age : A longer dosing interval, e. g . 10 mg 6 to 8 hourly.
Injection : 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 than 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 than 50 kg of body weight: one dose of 15 mg.
Paediatric patients (2 to 16 years of age):
IM Dosing: One dose of 1mg/kg up to a maximum of 30 mg.
IV Dosing: One dose of 0.5mg/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 **Eurolac®** 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 **Eurolac®** 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.
Ketorolac Tromethamine is for administration by intramuscular or bolus intravenous injection. The recommended initial dose of Ketorolac is 10 mg, followed by 10-30 mg every 4 to 6 hours as required . A total daily dose of 90 mg for non- elderly and 60 mg for the elderly, renaly-impaired patients and patients less than 50 kg should not be exceeded. The maximum duration should not be exceed two days .

Contraindications:
- a history of peptic ulcer or gastrointestinal bleeding.
- suspected or confirmed cerebrovascular bleeding.
- patients who have had operations with a high risk of hemorrhage or incomplete hemostasis.
- hemorrhagic diatheses, including coagulation disorders.
- a history of asthma.

Warnings:
Patients with hypersensitivity to Ketorolac Tromethamine or other NSAIDs and patients in whom Aspirin or other prostaglandin synthesis inhibitors induce allergic reactions (severe anaphylactic reactions have been observed in such patients)
- patients with the complete or partial syndrome of nasal polyps, angio edema or bronchospasm.
- concurrent tretment with other NSAIDs, oxepentifyline, probenecid or lithium salts.
- hypovolemia from any cause or dehydration.
- moderate or severe renal impairment (serum creatinine>160 micromol/l).

Side effects :
It is generally well tolerated. However, side effects like dry mouth, excessive thirst, psychotic reactions, convulsions, myalgia, hyponatremia, hyperkalemia, raised blood urea and creatinine, renal failure, hypertension, bradycardia, chest pain, purpura, post operative hemorrhage, haematoma, liver function changes etc. may occur.

Use in pregnancy and lactation:
The safety of **Eurolac®** in human pregnancy has not been established. It is therefore contraindicated during pregnancy, labor delivery. As **Eurolac®** has been detected in human milk at low levels; it is also contraindicated in mothers who are breast feeding.

Drug interactions:
Eurolac® interact with methotrexate, diuretics, ACE inhibitors, warfarin, heparin, digoxin, salicylate, lithium, aminoglycosides and other NSAIDs .

Storage condition:
Store in a cool and dry place. Protect from light .

Packaging :
Eurolac® 10 mg tablet : Each box contains 3x10 tablets in Alu-Alu blister pack .
Eurolac® 30 IV/IM injection: Each box contains 1 blister pack of 1 ampoule of 1 ml sterile Tromethamine USP 30 mg
Eurolac® 60 IM injection: Each box contains 1blister pack of 1 ampoule of 2 ml sterile solution for injection of Ketorolac Tromethamine 60 mg

Manufactured by
EURO Pharma Ltd.
In Pursuit of Excellence
Dhaka, Bangladesh