

Only for the use of Medical Professionals

Minolac[®]

Ketorolac Tromethamine USP

Description

Minolac[®] (Ketorolac Tromethamine) is a potent analgesic agent of the non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory and antipyretic properties. It inhibits synthesis of prostaglandin and may be considered as a peripherally acting analgesic. Minolac[®] is not an anesthetic agent and possesses no sedative or anxiolytic properties. It is not an opioid and has no known effects on opioid receptors.

Indication

Minolac[®] is indicated for the management of moderate to severe acute pain (usually in a severe acute post-operative pain, dental pain, cancer pain, gynecological pain, acute traumatic pain and migraine also).

Dosage and administration

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

Injection: Adult: The recommended initial dose of Minolac[®] is 10mg, followed by 10 to 30mg every 4 to 6 hours when required (the maximum daily dose is 90mg). In initial postoperative period, it may be given every 2 hours if needed. Elderly and patients weighing less than 50 kg maximum dose is 60mg daily. The maximum duration of treatment is 2 days. Injection should be given over no less than 15 seconds. For patients receiving Minolac[®] injection who are converted to tablets, the total combined daily dose should not exceed 90mg (60mg for the elderly and patients less than 50 kg) of which the oral component should not exceed 40mg on the day of change parenteral to oral.

Special dosage instructions: *Oral: Patients >65 years of age :* A longer dosing interval, e.g. 10mg 6 to 8 hourly. *Injection : IM Dosing: Patients <65 years of age:* One dose of 60mg. Patients 65 years of age, renally impaired and/or less than 50 kg (110 lbs) of body weight: One dose of 30mg. *IV Dosing: Patients < 65 years of age:* One dose of 30mg. Patients 65 years of age, renally impaired and/or less than 50 kg (110 lbs) of body weight: One dose of 15mg. *Paediatric patients (6 months and above):* Initially 0.5- 1 mg/Kg (max. 15 mg), then 0.5 mg/Kg (max. 15 mg) every 6 hours as required; max. 60 mg daily (Intravenously, over at least 15 seconds).

Contra-indications

- 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-like reactions have been observed in such patients)
- Patients with the complete or partial syndrome of nasal polyps, angio edema or bronchospasm
- Concurrent treatment with other NSAIDs, oxpentifyline, probenecid or lithium salts
- Hypovolemia from any cause, or dehydration
- Moderate or severe renal impairment (serum creatinine > 160 mmol/l).

Side effects

It is generally well tolerated. However, side effects like dry mouth, excessive thirst, psychotic reactions, convulsion, 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 Minolac[®] in human pregnancy has not been established. It is therefore contraindicated during pregnancy, labor or delivery. As Minolac[®] has been detected in human milk at low levels; it is also contraindicated in mothers who are breast feeding.

Drug interactions

Minolac[®] interact with Methotrexate, diuretics, ACE inhibitors, Warfarin, Heparin, Digoxin, Salicylate, lithium, aminoglycosides and other NSAIDs. Pharmaceutical precautions: Store in a cool & dry place. Protect from light.

Presentation

Minolac[®] Tablet: Each tablet contains Ketorolac Tromethamine USP 10 mg. Minolac[®] 10 Injection: Each ml contains Ketorolac Tromethamine USP 10 mg. Minolac[®] 30 Injection: Each ml contains Ketorolac Tromethamine USP 30 mg. Minolac[®] 60 Injection: Each 2 ml contains Ketorolac Tromethamine USP 60 mg.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Package quantities

- Minolac[®] 10 mg Tablets: Carton of 40 tablets in Alu-Alu blister.
- Minolac[®] 10 mg injection: Carton of 1 ampoule with a 3 ml/cc disposable syringe.
- Minolac[®] 30mg Injection: Carton of 1 ampoule with a 3 ml/cc disposable syringe.
- Minolac[®] 60mg Injection: Carton of 1 ampoule with a 3 ml/cc disposable syringe.

® Registered Trade Mark



ACI Limited