

Minolac®

Ketorolac Tromethamine

Composition

Minolac® 10 mg tablets: Each tablet contains Ketorolac Tromethamine USP 10 mg.

Minolac® 10 mg injection: Each ml contains Ketorolac Tromethamine USP 10 mg.

Minolac® 30 mg injection: Each ml contains Ketorolac Tromethamine USP 30 mg.

Minolac® 60 mg injection: Each 2 ml contains Ketorolac Tromethamine USP 60 mg.

Pharmacology

Minolac® is the preparation of Ketorolac Tromethamine which 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).

Dose and administration

Route of administration: **Minolac®** tablet should be taken in oral route and **Minolac®** injection should be taken in intravenous or intramuscular route.

Oral: Adult- The recommended oral dose of **Minolac®** is 10 mg 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 5 days) and are not recommended for chronic use.

Injection: Adult- The recommended initial dose of **Minolac®** is 10 mg, followed by 10 to 30 mg every 4 to 6 hours when required (the maximum daily dose is 90 mg). In initial post-operative period, it may be given every 2 hours if needed. Elderly and patients weighing less than 50 kg maximum dose is 60 mg 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 90 mg (60 mg for the elderly and patients less than 50 kg) of which the oral component should not exceed 40 mg on the day of change parenteral to oral.

Special dosage instructions

Oral: Patients > 65 years of age- A longer dosing interval, e.g., 10 mg 6 to 8 hourly.

Injection (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 (110 lbs) of body weight: One dose of 30 mg.

Injection (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 (110 lbs) of body weight: One dose of 15 mg.

Contraindication

Ketorolac is contraindicated in patients with known hypersensitivity to ketorolac or any components of this product. It is also contraindicated in patients with 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 and a history of asthma.

Warning and precaution

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, angioedema or bronchospasm, concurrent treatment with other NSAIDs, oxpentifyline, probenecid or lithium salts, patients with hypovolemia from any cause or dehydration, patients with moderate or severe renal impairment (serum creatinine > 160 µmol/l) should use this medication carefully.

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, hematoma and liver function changes.

Use in pregnancy and lactation

Pregnancy: The safety of ketorolac tromethamine in human pregnancy has not been established. It is therefore contraindicated during pregnancy, labor or delivery.

Lactation: As ketorolac tromethamine has been detected in human milk at low levels; it is also contraindicated in mothers who are breast feeding.

Use in children and adolescents

The safety and effectiveness of ketorolac tromethamine in pediatric patients below 16 years of age have not been established.

Drug interaction

Drug interaction with medication: Ketorolac tromethamine interacts with methotrexate, diuretics, ACE inhibitors, warfarin, heparin, digoxin, salicylate, lithium, aminoglycosides and other NSAIDs.

Drug interaction with food and others: Not applicable.

Overdose

Patients should be managed by symptomatic and supportive care following a NSAIDs overdose. There are no specific antidotes. Emesis and/or activated charcoal and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large oral overdose.

Storage

Store in a cool and dry place protected from light. Keep away from the reach of children.

Packing

Minolac® 10 mg tablets: Carton of 20 tablets in blister (For export).

Minolac® 10 mg tablets: Carton of 40 tablets in blister.

Minolac® 10 mg injection: Carton of 10 ampoules.

Minolac® 30 mg injection: Carton of 5 ampoules.

Minolac® 60 mg injection: Carton of 5 ampoules.

® Registered Trade Mark



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