

Rolac®

(Ketorolac Tromethamine USP)



DESCRIPTION

Rolac® contains Ketorolac Tromethamine which is a member of the pyrrolopyrrole group of nonsteroidal anti-inflammatory drugs (NSAIDs) that exhibits analgesic, anti-inflammatory and antipyretic activity. It has more pronounced analgesic activity than most NSAIDs. Ketorolac inhibits synthesis of prostaglandins and may be considered a peripherally acting analgesic. Ketorolac Tromethamine 3mg intramuscularly appears to be similar in efficacy to morphine 12 mg and superior to pethidine 100 mg. It has no opioid activity and thus does not present a problem of addiction.

COMPOSITION

Rolac® Tablet : Each film coated tablet contains Ketorolac Tromethamine USP 10mg.

Rolac®-10 Injection : Each ml contains Ketorolac Tromethamine USP 10mg.

Rolac®-30 Injection : Each ml contains Ketorolac Tromethamine USP 30mg.

Rolac®-60 Injection : Each 2ml contains Ketorolac Tromethamine USP 60mg.

INDICATIONS

Rolac® ampoules are indicated for the short-term management of moderate to severe acute postoperative pain. Rolac® tablets are indicated for the short-term management of moderate postoperative pain.

DOSAGE AND ADMINISTRATION

Rolac® ampoules are for administration by intramuscular or bolus intravenous injection.

Bolus intravenous doses should be given over not less than 15 seconds, Rolac® ampoules should not be used for epidural or spinal administration.

The time to onset of analgesic effect following both I.V. and I.M. administration is similar and is approximately 30 minutes, with maximum analgesia occurring within 1 to 2 hours. The medium duration of analgesia is generally 4 to 6 hours dosage should be adjusted according to the severity of the pain and the patient response.

Duration of treatment: The administration of continuous multiple daily doses of Rolac® intramuscularly or intravenously should not exceed 2 days because adverse events may increase with prolonged usage. There has been limited experience with dosing for longer periods since the vast majority of patients have transferred to oral medication or no longer require analgesic therapy after this time. Rolac® tablets are recommended for short-term use only (up to 7 days) and are not recommended for chronic use.

Adults: Ampoules: The recommended initial dose of Rolac® is 10 mg, followed by 10-30 mg every 4 to 6 hours as required. In the initial postoperative period, Rolac® may be given as often as every 2 hours if needed. The lowest effective dose

should be given. A total daily dose of 90 mg for non-elderly and 60 mg for the elderly, renal-impaired patients and patients less than 50 kg should not be exceeded. The maximum duration of treatment should not exceed 2 days.

Tablets: The recommended oral dose of Rolac® is 10 mg every 4 to 6 hours for pain as required. Doses exceeding 40 mg per day are not recommended.

For patients receiving Rolac® ampoules, and who are converted to Rolac® tablets, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, renal-impaired patients and patients less than 50 kg) and the oral component should not exceed 40 mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

Special dosage instruction : Elderly patients : Ampoules: For patients over 65 years, the lower end of the dosage range is recommended; a total daily dose of 60 mg should not be exceeded (see Precautions).

Tablets: A longer dosing interval, e.g. 6-8 hours, is advisable in the elderly. The lower end of the dosage range is recommended for patients over 65 years of age.

Children: Safety and efficacy in children have not been established. Therefore, Rolac® is contraindicated for use in children under 16 years of age.

Renal impairment : Since Ketorolac Tromethamine and its metabolites are excreted primarily by the kidney, Rolac® is contraindicated in moderate to severe renal impairment (serum creatinine > 160 µmol/l); patients with lesser renal impairment should receive a reduced dose (not exceeding 60 mg per day I.V. or I.M.) and their renal status should be closely monitored.

Combination treatment : (see also Incompatibilities) Opioid analgesics (e.g. morphine, pethidine) may be used concomitantly and may be required for optimal analgesic effect in the early postoperative period when pain is most severe. Ketorolac Tromethamine does not interfere with opioid binding and does not exacerbate opioid-related respiratory depression or sedation. When used in association with Rolac® ampoules, the daily dose of opioid is usually less than that normally required. However, opioid side effects should still be considered, especially in day-case surgery.

CONTRAINDICATIONS

- a history of peptic ulcer or gastrointestinal bleeding
- suspected or confirmed cerebrovascular bleeding
- hemorrhagic diatheses, including coagulation disorders
- 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, oxpentifylline, probenecid or lithium salts
- hypovolemia from any cause or dehydration
- moderate or severe renal impairment (serum creatinine > 160

µmol/l)

- a history of asthma
- patients who have had operations with a high risk of hemorrhage or incomplete homeostasis
- patients on anticoagulants including low-dose heparin (2500- 5000 units 12 hourly)
- during pregnancy, labor, delivery or lactation
- children under 16 years of age.

OVERDOSAGE

Doses of 360 mg given intramuscularly over and 8 hour interval for 5 consecutive days have caused abdominal pain and peptic ulcers which have healed after discontinuation of dosing. Two patients recovered from unsuccessful suicide attempts.

One patient experienced nausea after 210 mg Ketorolac, and the other hyperventilation after 300 mg Ketorolac.

SIDE EFFECTS/ADVERSE REACTIONS

Gastro-intestinal : Nausea, dyspepsia, gastro-intestinal pain, abdominal discomfort bowel changes, gastritis, diarrhoea eructation, constipation, flatulence, fullness, melaena, peptic ulcer, rectal bleeding, stomatitis, vomiting, hemorrhage, perforation, pancreatitis.

Central nervous/musculoskeletal systems : Drowsiness, dizziness, headache, sweating, dry mouth, nervousness, paraesthesia, functional disorders, abnormal thinking, depression, euphoria, mental and sensory changes, convulsions, excessive thirst, inability concentrate, insomnia, stimulation, vertigo, abnormal taste and vision, myalgia, abnormal dreams, hallucinations, hyperkinesia, hearing loss, tinnitus, aseptic meningitis.

Renal : Increased urinary frequency, oliguria, acute renal failure, hyponatraemia, hyperkalaemia, haemolytic uraemic syndrome, Flank pain (with or without haematuria), raised serum urea, creatinine and urinary symptoms & acute renal failure.

Cardiovascular/haematological : Flushing, bradycardia, pallor, purpura, thrombocytopenia, hypertension, inhibition of platelet aggregation & prolonged bleeding time, postoperative wound hemorrhage, and haematoma.

Respiratory : Dyspnoea, asthma, pulmonary edema.

Dermatological : Pruritus, urticaria, Lyell's syndrome, Stevens Johnsons syndrome, exfoliative dermatitis, maculopapular rash.

Hypersensitivity reactions : Anaphylaxis, bronchospasm, laryngeal edema, hypotension, flushing and rash. Such reactions may occur in patients with or without known sensitivity to ketorolac or other NSAIDs.

Other : Asthenia, edema, weight gain, abnormalities of liver function tests injection site pain (rare).

PRECAUTIONS

Physicians should carefully weigh the potential risks and benefits of its use on a long term basis. Patients should be instructed to watch for signs of serious GI adverse events and they should be monitored more closely than if they were on another NSAID.

For the short-term management of pain (other than postoperative). Rolac® I.M. is not recommended for longer use (more than 5 days) because of the possibility of increased frequency and severity of adverse reactions associated with the recommended doses and Rolac® tablet is not recommended for use beyond 7 days & is not recommended for chronic use. Dose should be reduced in elderly and in those weighing less than 50kg. Rolac® injection is not recommended as a preoperative medication for support of anaesthesia because it inhibits platelet aggregation and may prolong bleeding time and because it possesses no sedative or anxiolytic properties.

In patients with symptoms and signs suggesting liver dysfunction or in whom an abnormal liver test has occurred as a result of Ketorolac Tromethamine therapy the administration of the drug should be discontinued.

High oral doses (e.g. 80 or 120 mg/day) are not recommended because risk of serious adverse events are greater with daily dose exceeding the recommended 40 mg (4 tablets) oral per day. Serious G.I. toxicity such as bleeding ulceration and perforation can occur at any time with or without warning symptoms in patients with NSAIDs.

Physicians should be aware that in some patients pain relief may not occur until upwards of 30 minutes after I.V. or I.M. administration, Physicians should be aware of the pharmacological similarity of ketorolac to other NSAIDs that inhibit cyclo-oxygenase and the risk of bleeding particularly in the elderly. It should not be used for epidural or spinal administration.

USE IN PREGNANCY AND LACTATION

It is detected in human milk. Safety in pregnancy has not been established. It is not recommended during pregnancy, labour or delivery and in mother who are breast-feeding.

PACKAGING

Rolac® 10mg Tablet : Box containing 5x14'S/2x10'S/3x10'S/4x10'S/ 4x14'S tablets of blister pack.

Rolac®-10 injection : Box containing 1x5'S 1ml Ampoules in blister pack.

Rolac®- 30 injection : Box containing 6x1'S 1ml Ampoules & 6 disposable syringes.

Rolac®- 60 injection : Box containing 2x1'S 2ml Ampoules & 2 disposable syringes.

PHARMACEUTICAL PRECAUTIONS

Store in a Cool & Dry Place, Protected from light.

Keep out of the reach of children.

® Trade Mark

Manufactured by
Renata Limited
Mirpur, Dhaka, Bangladesh

Tablet (10mg) & Injection (10mg, 30mg & 60mg)

Manufactured by
Renata Limited
Rajendrapur, Gazipur, Bangladesh

Tablet (10mg)
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