LOPIROX®

Piroxicam

www.exirpharma.com

Description

Lopirox® is a member of the oxicam series of compounds being a non-steroidal anti-inflammatory agent with analgesic and antipyretic properties and a particularly long half-life.

Clinical pharmacology

Lopirox® is effective in relieving pain and reducing fever in febrile patients. In patients with rheumatoid arthritis Lopirox® relieves pain and reduces joint swelling but rarely affects the ESR or other measures of disease activity. Lopirox® inhibits prostaglandin (thromboxane) synthesis in the platelets, rendering them less sticky.

Pharmacokinetics

Oral absorption	~100%
Plasma half-life	50 hours
Volume of distribution	0.14 L/kg
Plasma protein binding	99%

Indication

1. Osteoarthritis
2. Rheumatoid arthritis
3. Ankylosing spondylitis
4. Acute attacks of gout
5. Dysmenorrhea

Contraindication

- Lopirox® is contraindicated in patient with known hypersensitivity to Piroxicam.
- Lopirox® shouldn't be given to patients who have experienced asthma, utrica or allergic-type reactions after taking Aspirin or other NSAIDs.

Note: sever, rarely fatal, anaphylactic-like reaction to NSAIDs have been reported in such patients.

Precaution

- Lopirox® can't be expected to substitute for corticosteroids or to treat corticosteroid insufficiency.
- Caution in patient with infection, since symptoms such as fever and inflammation may be masked.
- Lopirox® should be used with caution in patients with asthma or allergic disorders.
- Lopirox® has been associated with acute attacks of porphyria and is considered unsafe in porphyric patients.
- In cases with advanced kidney disease, treatment with Lopirox® is not recommended.

Pregnancy

pregnancy category C and D (according to different stages). Safety for use during pregnancy has not been established; using is not recommended. There are no adequate and well-controlled studies in pregnant women. NSAIDs are category D if used in the third trimester or near delivery. Taking Lopirox® during third trimester has caused clouser of the ductus arteriosies, inhibition of platelet function, resulting in bleeding renal function impairment or failure with oligohydraminas, gastrointestinal bleeding or perforation, and myocardial degeneration changes in fetuses when given to pregnant women during the third trimester.

Breast feeding

Lopirox® is excreted into human milk. The presence in breast milk has been determined during initial and long term conditions.

Lopirox® is not recommended for use in nursing mothers because of effects on the infant's cardiovascular system. Studies in rats have shown that Piroxicam causes a dose-dependent inhibition of lactation.

Dosage

In rheumatic disorders a usual inital dose of Lopirox® by mouth is 20 mg daily as a single dose. Daily maintenance doses may vary between 10 and 30 mg given in single or divided doses.

In acute musculoskeletal conditions an initial dose of 40 mg daily may be given for 2 days followed by 20 mg daily for a total of 1 to 2 weeks.

In acute gout, the usual dose being 40 mg daily for 5 to 7 days.

Lopirox® is given in similar doses as on a short-term basis by intramuscular injection.

- Note: this dose may be reduced to 10 mg daily in elderly patients, study in geriatric patients have shown a tendency toward increased elimination half-life and steady-state plasma concentration in these patients, specially elderly females. Dosage recommendations and indications for use in children have not been established.
- Note: Avoid injection to children below 15 years.

Patient consultation

- Caution patients to take protective measures (i.e., sunscreens, protective clothing) against UV or sunlight until tolerance is determined.
- Avoid Aspirin and alcoholic beverages while taking medication.
- Take this medicine immediately after meals or with food or antacids to reduce gastrointestinal irritation, alert patients for the signs and symptoms of ulcerations and bleeding.

Patient monitoring

- Monitoring of blood urea nitrogen (BUN), creatinine concentrations of serum, or potassium concentration of serum may be required at periodic intervals during therapy, specially in patients with hepatic or renal function impairment or those taking diuretics concurrently.
- Hematocrit determination, hemoglobin determination, or stool intervals to detect blood loss during prolonged therapy, depending on the individual patient's risk of developing gastrointestinal toxicity.
- Liver function tests, specially determination of transaminase (AST and ALT) values may be required at periodic interval during Lopirox® therapy.
- Ophthalmologic examination may be required if vision problems such as blurred vision occur during therapy
- Upper gastrointestinal diagnostic tests recommended for patients with persistent or sever dyspepsia or other signs of possible gastrointestinal toxicity.

Warning

- In cases of advanced kidney disease, treatment with Lopirox® is not recommended.
- Patients should be advised to notify their physician if they become pregnant or intend to become pregnant.
- Patients should be advised to notify their physician if they are breast feeding and infant.
- Notifying physician immediately if influenza- like symptoms (chills, fever, or muscle aches and pains) appear.

Interaction

- Concurrent use of Lopirox® with Acetaminophen may increase the risk of adverse renal effects.
- Lopirox® may increase the plasma concentration of Cyclosporine, digitalis glycosides, Lithium and Methotrexate.
- Concurrent use of Lopirox® with alcohol, corticosteroids, potassium supplements, anticoagulants (Coumarin or indandione- derivative), Heparin, thrombolytic agents, Aspirin, Colchicine, platelet aggregation inhibitors, and two or more concurrently usage of NSAIDs may increase risk of gastrointestinal side effects, including ulceration or hemorrhage.
- Lopirox® may increase the hypoglycemic effect of oral antidiabetic agents or Insulin.
- Lopirox® may increase the risk of nephrotoxicity if given with ACE inhibitors, Cyclosporine, Tacrolimus, or diuretics.
- Leukopenic and thrombocytopenic effects of bone marrow depressants may be increased with concurrent or recent therapy of Lopirox®.
- Concurrent use of Lopirox® with photosensitizing medications may cause additive photosensitizing effects.
- Ritonavir may increase the concentrations and possibly the toxicity of Lopirox® by inhibiting its metabolism.

Laboratory value alteration

- Lopirox® may increase or decrease blood glucose concentration.
- Lopirox® may increase protein of urine (including albumin) concentrations.
- Laboratory test values like bleeding time may be prolonged by Lopirox®.

Adverse reactions

The most frequent adverse reactions are:

Headache, dizziness, rash, pruritus, edema, cramps, diarrhea, nausea, vomiting, constipation, flatulence, dyspepsia, heartburn, anorexia, gross bleeding, peptic ulcer, anemia, renal function impairment

Incidence less frequent or rare:

Palpitation, hypertension, tachycardia, arrhythmia, syncope, asthenia, depression, tremor, confusion, fatigue, convulsions, urticaria, Stevens-Johnson syndrome, photosensitivity, dry mouth, rectal bleeding, hematemesis, dysuria, polyuria, hematuria, cystitis, oliguria, proteinuria, purpura, leucopenia, aplastic anemia, angioedema, hyperglycemia, hyperkalemia, dyspnea, asthma, blurred vision, influenza-like disease and chills.

Overdose

Discontinuing or temporarily suspending administration. Monitoring the patient and treating observed symptoms.

Note: Forced diuresis, haemodialysis, or haemoperfusion are unlikely to be benefit for NSAIDs over dosage, although haemodialysis may be required if oliguric renal failure develops.

Storage and stability condition

- Store below 30 °C.
- Protect from light and freezing.
- Keep inside the box.
- Keep out of the reach of children

Packaging

- Capsule:

Each capsule contains: Piroxicam 10 mg

- Ampoule:

Each ampoule (1 ml) contains: Piroxicam 20 mg

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