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PROFENID

Sanofi-Aventis

Composition

contains as active substance ketoprofen (INN). Tablets and Suppositories of 100 mg; solution for injection IM of 100 mg are available.

Properties

Ketoprofen is a non-steroidal anti-inflammatory drug belonging to the propionic group, derived from aryl-carboxylic acid. It possesses an anti-inflammatory, analgesic and antipyretic activity; it inhibits prostaglandin synthesis and has an inhibitory action on platelet aggregation.

Indications

They are limited to adults and children above 15 years old: - Long-term symptomatic treatment of chronic inflammatory rheumatism; especially rheumatoid arthritis, ankylosing spondylitis or related syndromes such as Reiter's syndrome and psoriatic rheumatism; certain forms of painful and disabling osteoarthritis. -Short-term symptomatic treatment of acute of: periarticular rheumatism (acute painful shoulder, tendinitis, etc.), crystal-deposition disease, osteoarthritis, back pain, severe nerve root pain.

Dosage and administration

According to the dosage and presentation existing in the Market. No reduction of ketoprofen absorption has been observed in the case of coprescription of aluminium gels.

Absolute Contraindications

- Known allergy to ketoprofen and substances with a similar activity: acute asthma has been observed in some patients, especially those allergic to aspirin.
- Active gastroduodenal ulcer, severe liver and kidney failure.
- **Pregnancy:** Last trimester of pregnancy. It is not recommended to administer ketoprofen during the first trimester of pregnancy due to the possible teratogenic risk, although no particular malformations have been reported in man. However, complementary epidemiological studies are required to confirm or refute this possibility. All inhibitors of prostaglandin synthesis can induce foetal cardiopulmonary hypertension with premature closure of the ductus arteriosus and renal toxicity during the 3rd trimester of pregnancy and prolonged bleeding time, in mother and child, at the end of pregnancy. Consequently, the use of NSAIDs is formally contraindicated during the last trimester.
- **Nursing mothers:** In the absence of any pharmacological data, ketoprofen is not indicated in nursing mothers.
- Children under the age of 15 years.

Warning

Because of the possible seriousness, the patient should be especially monitored for the onset of gastrointestinal symptoms. Discontinue treatment in the event of gastrointestinal haemorrhage.

Asthma patients presenting chronic rhinitis, sinusitis and/or nasal polyposis may develop allergic reactions due to intake of aspirin and/or NSAIDs.

Precautions

- History of gastroduodenal ulcer.
- At the start of treatment, careful monitoring of urine volume and kidney function in heart failure, cirrhotic and nephrotic patients, patients treated with diuretics, patients with chronic renal failure and particular elderly subjects.
- Possible reduction of the efficacy of IUD.

Drug Interactions

Coprescriptions to be avoided:

oral anticoagulants, heparin: increased risk of haemorrhage.

Sulfonylureas: Potentiation of the effect.

Lithium: raised serum lithium levels.

Methotrexate: increased haematological toxicity.

Diuretics: Decreased activity.

Ticlopidine; increased platelet antiaggregant activity.

Other NSAIDs: Increased risk of ulcer and haemorrhage.

Alertness and Driving

- Possibility of dizziness.

Adverse effects

- Gastrointestinal manifestations: Usually, gastrointestinal discomfort, gastric burning, nausea, vomiting, constipation, diarrhoea; more serious: peptic ulcer, gastrointestinal haemorrhage, intestinal perforation.

At an oral dose of 200 mg per day: Increased occult intestinal blood loss.

- Headache, vertigo, drowsiness.
- Dermatological and respiratory hypersensitivity reactions (possibility of asthma attack, particularly in subjects allergic to aspirin and other NSAIDs). Moderate fall in haemoglobin level; a few rare cases of minor leukopenia have been reported.
- In the presence of renal impairment (see Precautions).
- Exceptionally, bullous dermatitis.

Overdosage

In the case of accidental or deliberate massive absorption, gastric washing (oral formulation) and symptomatic treatment should be instituted.