Only for the use of Medical Professionals

Ketron®

Ketoprofen

Description

Ketron® is a preparation of Ketoprofen. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). It is a strong inhibitor of prostaglandin synthetase and potent analgesic agent. Ketoprofen possesses powerful anti-inflammatory, antipyretic, anti-bradykinin and lysosomal membrane stabilizing properties.

Indications

Ketron® is recommended in the management of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute articular and periarticular disorders (bursitis, capsulitis, synovitis, tendonitis), fibrositis, cervical spondylitis, low back pain, (strain, lumbago, sciatica), gout and dysmenorrhoea. **Ketron®** reduces joint pain and inflammation and facilitates increase in mobility and functional independence. It is also indicated in the treatment of post-operative pain.

Dosage and administration

Adult: The dose of Ketron is 50-100 mg daily, taken with food to minimize gastrointestinal disturbance. For rheumatic disease, 100-200 mg daily in 2-4 divided doses with food. For pain and dysmenorrhoea, 50 mg upto 3 times daily.

The usual dose of **Ketron® SR** is 100mg to 200 mg once daily, it should be taken with food. The dose depends on the patient's weight and on the severity of symptoms.

Elderly patient: As with other medications, it is generally advisable to begin Ketoprofen at the lower end of the dosage range and maintain such patients on the lowest effective dosage.

Children: Ketoprofen is not recommended for children 12 years since safety and efficacy in this age group have not been established.

Use in pregnancy and lactation

No embryopathic effects have been demonstrated in animals and there is epidemiological evidence of the safety of Ketoprofen in human pregnancy. Nevertheless, it is recommended to avoid Ketoprofen unless considered essential. Trace amounts of Ketoprofen are excreted in breast milk; avoid use of ketoprofen unless considered essential.

Side-effects

Minor adverse events are gastrointestinal effects such as indigestion, diarrhea, dyspepsia, nausea, constipation, heart burn and various types of abdominal discomfort. Major gastrointestinal adverse effect such as peptic ulceration, haemorrhage or perforation may rarely occur.
Major adverse effects involving other organ systems such as haematological reactions, hepatic and renal damage, dermatological reactions, bronchospasm and anaphylaxis are exceedingly rare. In all cases of major adverse events Ketoprofen should be withdrawn at once.

Contraindications

Ketoprofen is contraindicated in patients with known hypersensitivity to ketoprofen or to any of its ingredient. Ketoprofen is also contraindicated in active peptic

ulceration, a history of recurrent peptic ulceration or chronic dyspepsia, severe renal dysfunction and severe hepatocellular dysfunction. Ketoprofen should not be given to patients sensitive to aspirin or other non-steroidal anti-inflammatory agents. Severe bronchospasm might be precipitated in these patients and in those suffering from or with a history of bronchial asthma or allergic diseases.

Precautions
Ketoprofen should be used with caution in patients with a history of recurrent peptic ulceration or chronic dyspepsia and impaired renal function. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.

Drug Interactions
Ketoprofen is highly protein-bound. Concomitant use of other protein-binding drugs, e.g. anticoagulants, sulphonamides, hydantoins might necessitate modification of dosage in order to avoid increased levels of such drugs resulting competition for plasma-protein binding sites. Similar acting drugs such as aspirin, or other non-steroidal anti-inflammatory agents should not be administered concomitantly with Ketoprofen as the potential for adverse reactions is increased. Serious interactions have been recorded after the use of high dose methotrexate with non-steroidal anti-inflammatory agents including Ketoprofen.

Over dosage
Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Gut decontamination may be indicated in patients with symptoms seen within 4 hours (longer for sustained release products) or following a large overdose (5 to 10 times the usual dose). Administration of activated charcoal in an attempt to reduce absorption of ketoprofen should be considered. Forced diuresis, alkalinization of the urine, haemodialysis or haemoperfusion would probably not be useful due to ketoprofen's high protein binding.

Pharmaceutical precautions
Store in a cool dry place. Protect from light.

Presentation
Ketron® 50mg tablet: Each enteric coated tablet contains Ketoprofen BP 50 mg.
Ketron® SR 100mg: Each Capsule contains Ketoprofen BP 100 mg in sustained release pellets.
Ketron® SR 200mg: Each Capsule contains Ketoprofen BP 200 mg in sustained release in pellets.

Package quantities
Ketron® 50mg tablet: Carton of 50 tablets in Alu-PVC blister.
Ketron® SR 100 mg Capsule: Carton of 50 Capsules in Alu-PVC blister.
Ketron® SR 200 mg Capsule: Carton of 30 Capsules in Alu-PVC blister.

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