Rapidus®

Diclofenac Potassium Tablets

Composition:

Rapidus 25: Each coated tablet contains Diclofenac Potassium 25 mg.
Rapidus 50: Each coated tablet contains Diclofenac Potassium 50 mg.
Excipients: Dibasic calcium phosphate anhydrous, sodium starch glycolate, copolyvidone, talc, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose, polyethylene glycol, simethicone, E171 and E172.

Properties:

Rapidus is a brand name of diclofenac potassium tablet which is a nonsteroidal anti-inflammatory drug (NSAID) having pronounced anti-rheumatic, anti-inflammatory and analgesic effects. As with other NSAIDs, exact mode of action of diclofenac is not known, however, its ability to inhibit prostaglandin synthesis may be involved in its anti-inflammatory and pain relieving activities.
Diclofenac is rapidly and almost completely absorbed from **Rapidus** Tablets. These properties make it recommended for the treatment of acute painful and inflammatory conditions in which rapid onset of action is required.
The peak plasma concentration is reached in 20-60 minutes after administration. The plasma half-life is 1-2 hours. Diclofenac is eliminated as metabolites. About 60% of the administered dose is excreted in the urine and the remaining in the bile.

Indications:

Rapidus is indicated for the short term treatment of the following acute conditions where a rapid onset of effect is particularly important:
- Painful post-traumatic inflammatory conditions.
- Post-operative inflammation and pain such as dental or orthopaedic surgery.
- Painful and/or inflammatory conditions in gynaecology such as primary dysmenorrhoea or adnexitis.
- Painful syndromes of the vertebral column.
- Non-articular rheumatism.

Contraindications:

Rapidus is contraindicated in patients with peptic ulcer or known for hypersensitivity to diclofenac or other NSAIDs. Like other NSAIDs, diclofenac is contraindicated for patients in whom attacks of urticaria, asthma, or acute rhinitis have been precipitated by aspirin or other prostaglandin synthetase inhibitors.

Precautions:

Appropriate diagnosis and careful medical monitoring are required in patients with coagulation defects, porphyria, peptic ulcer, ulcerative colitis and gastrointestinal disorders.
Rapidus should be used under medical supervision in patients with impaired cardiac, renal or hepatic functions, in the elderly and patients taking diuretics. Patients experiencing dizziness or blurred vision during treatment with **Rapidus** should not drive or operate machinery.

Interactions with other drugs:

Diclofenac may increase serum levels of digoxin or lithium when given together with preparations containing these substances. Some NSAIDs can inhibit the effect of diuretics. Although clinical studies do not appear to suggest that diclofenac affects the action of anticoagulants, an increased risk of haemorrhage in patients receiving diclofenac and anticoagulants concomitantly have been reported in isolated cases. Co-administration of NSAIDs with methotrexate or cyclosporin may increase their toxicity.
Clinical studies have shown that diclofenac can be given concomitantly with oral antidiabetic agents without influencing their clinical effect, however, an adjustment in the dosage of antidiabetic drugs during treatment with diclofenac may be required.

Warnings:

Safety of using diclofenac during pregnancy has not been established, therefore, **Rapidus** should not be given during pregnancy especially in the 3rd trimester due to the risk of premature closure of the ducts arteriosus and suppression of uterine contractility.
cardiovascular risk:
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events mycardial infarction, and stroke, which can be fatal.
This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
Diclofenac is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) Surgery.
Gastrointestinal risk:
NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Dosage and Administration:

The usual recommended adult daily dose is 100-150 mg in 2-3 divided doses. In milder cases and for children over 14 years of age the daily dose is 75-100 mg in 3-4 divided doses.
In primary dysmenorrhoea the initial dose should be 50-100 mg, if neccessary, this dose can be raised over a number of menstrual cycles to a maximum of 200 mg daily.
The tablets should be swallowed with liquid.

Overdosage:

The following therapeutic measures should be taken in case of overdosage: Gastric emptying is generally recommended as soon as possible. Syrup of ipecac and gastric lavage are the most commonly employed methods. Administration of activated charcoal is indicated after completion of emesis or lavage. Supportive and symptomatic treatment is indicated for complications such as respiratory depression, hypotension, gastrointestinal irritation, convulsions and renal failure.

Side Effects:

Generally diclofenac is well tolerated, the most common gastrointestinal side effects include: dyspepsia, nausea, vomiting, diarrhea and abdominal cramps. Rarely peptic ulcer and gastrointestinal bleeding have occurred. Some aspirin sensitive patients may develop hypersensitivity reactions such as bronchospasm, rashes and angioedema, fluid retention, headache, dizziness and hearing disturbances such as tinnitus. In rare cases blood disorders, reversible acute renal failure, renal papillary necrosis, alveolitis, hepatic damage, porphyria, elevation of liver enzymes, pancreatitis and photosensitivity have been reported.
Consult your pharmacist or physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15 - 30 °C).
Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentations:

Rapidus 25: Pack of 10 and 20 coated tablets.
Rapidus 50: Pack of 10 and 20 coated tablets.
Hospital packs are available.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.

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