DICLOFENAC POTASSIUMTABLETS
NEODOL- K

COMPOSITION:
Each sugar-coated tablet contains:
Diclofenac Potassium BP 50mg.

CHEMISTRY: Diclofenac Potassium is designated chemically as 2-[(2, 6-dichlorophenyl) amino] benzeneacetic acid, monopotassium salt.

PHARMACOLOGY: Diclofenac possesses analgesic, antipyretic and anti-inflammatory activities; it is an inhibitor of cyclooxygenase. In addition, Diclofenac appears to reduce intracellular concentrations of free arachidonate in leukocytes, perhaps by altering the release or uptake of the fatty acid.

Pharmacokinetics: Absorption: Diclofenac is rapidly and completely absorbed from the gastrointestinal tract, with measurable plasma levels being observed, in some fasting volunteers, within 10 minutes of dosing with Diclofenac Potassium. Peak plasma levels are achieved in approximately in one hour.
Distribution: Plasma concentrations of Diclofenac decline from peak levels in a biexponential fashion, with the terminal phase having a half-life of approximately 2 hours. Clearance and volume of distribution are about 350 mL/min and 550 mL/kg, respectively. More than 99 % of Diclofenac is reversibly bound to human plasma albumin.
Metabolism and Elimination: Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulphate conjugates of the metabolites. Approximately 65 % of the dose is excreted in the urine, and approximately 35% in the bile.

INDICATIONS AND USES: Diclofenac Potassium is indicated for acute and chronic treatment of signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. Diclofenac Potassium is indicated for the management of pain and primary dysmenorrhea.

CONTRAINDICATIONS: Diclofenac Potassium is contraindicated in patients with hypersensitivity to Diclofenac. Diclofenac Potassium should not be given to patients who have experienced asthma, urticarial, or other allergic-type reactions after taking aspirin or other Non Steroidal Anti-inflammatory Drugs. Severe, rarely fatal, anaphylactic-like reactions to Diclofenac have been reported in such patients.

The use of high dose diclofenac (150mg/day) for more than 4 weeks is contraindicated in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension.

SIDE EFFECTS / ADVERSE REACTIONS: Peptic ulcer or GI bleeding. Abdominal pain or cramps, headache, fluid retention, abdominal distention, diarrhoea, indigestion, nausea, constipation, flatulence and dizziness may occur.

Cardiac disorders
Uncommon*: Myocardial infarction, cardiac failure, palpitations, chest pain
*The frequency reflects data from long-term treatment with high dose (150mg/day)

Description of selected adverse drug reactions
Arteriothrombotic events
Meta-analysis and pharmacoepidemiological data point towards a small increased risk of arteriothrombotic events (for example myocardial infarction) associated with the use of diclofenac, particularly at a high dose (150 mg daily) and during long-term treatment.

PRECAUTIONS AND WARNING: *General:* Allergic Reactions: allergic reactions including anaphylaxis have been reported with Diclofenac Potassium. Fluid Retention and Edema has been observed in some patients.
Peptic ulceration and gastrointestinal bleeding have been reported in patients receiving Diclofenac. Physicians and patients should therefore remain alert for ulceration and bleeding in patients treated chronically with Diclofenac Potassium even in the absence of previous G.I tract symptoms. Elevations of one or more liver tests may occur during Diclofenac therapy.

Cardiovascular effects
Treatment with NSAIDs, including Diclofenac, particularly at high dose and in long term, may be associated with a small increased risk of serious cardiovascular thrombotic events (including myocardial infarction and stroke).

As the cardiovascular risks of Diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continues for more than 4 weeks. Patients should be advised to remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.

DRUG INTERACTIONS: Concomitant administration of Diclofenac potassium and Aspirin is not recommended. Ingestion of Diclofenac may increase serum concentrations of Digoxin and Methotrexate and increase Cyclosporine's nephrotoxicity. Diclofenac increases Lithium clearance level and increases Lithium plasma level. Concomitant treatment with potassium sparing diuretics may be associated with increased serum potassium levels.

USE IN PREGNANCY AND LACTATION: There are no adequate and well-controlled studies in pregnant women. Diclofenac Potassium should be used during pregnancy only if the benefits to the mother justify the potential risk to the fetus.
Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.

Nursing Mothers: Diclofenac Potassium has been found in the milk of nursing mothers. As with other drugs that are excreted in milk, it is not recommended for use in nursing women.
Paediatric Use: Safety and effectiveness of Diclofenac Potassium in children have not been established.

DOSAGE AND ADMINISTRATION:
Osteoarthritis: The recommended dosage is 100-150mg/day in divided doses.
Rheumatoid Arthritis: the dosage is 150-200mg/day in divided doses, 50 mg t.i.d, or q.i.d. Diclofenac Potassium.
Ankylosing Spondylitis: The recommended dosage is 100-125 mg/day administered as 25 mg q.i.d. with an extra 25 mg dose at bed time if necessary.
After satisfactory response has been obtained, dosage should be reduced to the minimum dose that provides continuing control of symptoms, usually 75 to 100 mg a day in three divided doses.
Analgesia and Primary Dysmenorrhea: Initial dose of 50 mg of Diclofenac Potassium, followed by 50 mg doses every 8 hours as needed.

Special populations
Established cardiovascular disease or significant cardiovascular risk factors
The use of high dose diclofenac (150mg/day) for more than 4 weeks is contraindicated in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If diclofenac treatment is needed, patients with established cardiovascular disease, uncontrolled hypertension or significant cardiovascular risk factors (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated only after careful consideration and at doses ≤ 100 mg daily if the treatment is for more than 4 weeks. As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, diclofenac should always be prescribed at the lowest effective daily dose and for the shortest duration possible.

OVERDOSAGE, SYMPTOMS AND ANTIDOTE: In case of acute over dosage, it is recommended that the stomach be emptied by vomiting or lavage.

STORAGE: Store below 25°C, in a dry place.

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