NEPOFEN TABLET/GEL

Generic name:	Diclofenac Sodium
Category:	Analgesic & Antirheumtatic
Composition/Presentation:	**NEPOFEN-50** Each film coated tablet contains Diclofenac Sodium BP 50 mg In blister pack of 30 Tablets x 10 Blisters **NEPOFEN-K** Each enteric coated tablet contains Diclofenac Potassium 50 mg In blister pack of 30 Tablets x 10 Blisters **NEPOFEN SR** Each film coated sustained release tablet contains Diclofenac Sodium 100 mg. In blister pack of 30 Tablets x 10 Blisters **NEPOFEN Gel** Diclofenac diethylamine BP…….1.16% **NEPOFEN PLUS Gel** Diclofenac Diethylamine BP ……1.16% w/w Virgin Linseed oil BP…….3.0% w/w Methyl Salicylate……....10.0% w/w Menthol…….5.0%w/w Benzyl Alcohol……1.0%w/w Available as Collapsible 30gm tube

MECHANISM OF ACTION

Diclofenac has shown anti-inflammatory, analgesic, and antipyretic activity. The anti-inflammatory effects of diclofenac may be due to the inhibition of prostaglandin synthesis.

PHARMACOKINETICS

Nepofen-50 and Nepofen K (enteric-coated) Tablets are in a pharmaceutical formulation that resists dissolution in the low pH of gastric fluid but allows a rapid release of drug in the higher pH-environment of the duodenum. Conversely, under fasting condition, diclofenac is completely absorbed from the gastrointestinal tract. However, due to first-pass metabolism, only about 50% of the absorbed dose is systemically available.

NEPOFEN-50 Tablets: Peak plasma levels are achieved in 2 hours in fasting normal volunteers, with a range from 1 to 4 hours. The extent of absorption of diclofenac is not significantly affected by food intake.

Distribution

Diclofenac diffuses into and out of the synovial fluid. Diffusion into the joint occurs when plasma levels are higher than those in the synovial fluid,

Metabolism and Elimination

Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulfate conjugates of the metabolites. Approximately 65% of the dose is excreted in the urine, and approximately 35% in the bile.

INDICATION

NEPOFEN (Diclofenac sodium and potassium) is indicated in Ankylosing Spondylitis, Osteoarthritis, Rheumatoid Arthritis. Beside the above indication Diclofenac potassium is also used in management of pain and dysmenorrhea.

DOSAGE

In child: 1 year or over in JUVENILE ARTHRITIS recommended dose is 1-3mg/kg body weight DAILY in divided doses.
Osteoarthritis: 100 to 150 mg/day: 50mg 2-3 times a day. Max 150mg/day.
Rheumatoid Arthritis: 100 to 200 mg/day:. 50mg 3-4 times a day. Max: 225mg/day.
Ankylosing Spondylitis: 100 to 125 mg/day:
Analgesia and Primary Dysmenorrhea: Starting dose is 50 mg t.i.d. The total daily dose should generally not exceed 150 mg.

ADVERSE REACTIONS

The most common side effects of Diclofenac are edema, fluid retention, abdominal cramps or pain, constipation, diarrhea, headache, indigestion and nausea.

PRECAUTIONS

Caution should be in liver or kidney disease, blood disorders, ulcers, heart disease, alcohol use, high blood pressure, eye disease or allergies, especially drug allergies.

CONTRAINDICATIONS

Diclofenac in all formulations, Nepofen, is contraindicated in patients with known hypersensitivity to diclofenac and diclofenac-containing products. Diclofenac should not be given to patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.

DRUG INTERACTIONS

Aspirin: Concomitant administration of diclofenac and aspirin is not recommended because diclofenac is displaced from its binding sites during the concomitant administration of aspirin, resulting in lower plasma concentrations, peak plasma levels, and AUC values.
Digoxin, Methotrexate, Cyclosporine: Diclofenac, like other NSAIDs, may affect renal prostaglandins and increase the toxicity of certain drugs. Ingestion of diclofenac may increase serum concentrations of digoxin and methotrexate and increase cyclosporine's nephrotoxicity.
Lithium: Diclofenac decreases lithium renal clearance and increases lithium plasma levels. In patients taking diclofenac and lithium concomitantly, lithium toxicity may develop.
Diuretics: Diclofenac can inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

For further information, please contact:
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