DICLOFENAC SODIUM INJECTION
NEODOL INJECTION

Composition: Each ml contains: Diclofenac Sodium BP 25 mg.

Description: Colourless clear liquid for IM injection.

Indications: Relief of pain and inflammation in condition such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, renal colic, acute gout.

Properties: Neodol injection is an anti-inflammatory and analgesic preparation. Diclofenac inhibits prostaglandin biosynthesis and in inflammation condition, relieves pain and reduce edema.

Adverse effects: Adverse effects are usually mild and transient. Frequently reported adverse effects are gastrointestinal disturbances, e.g., epigastric pain, nausea, vomiting and diarrohoea. Occasionally, papillary necrosis, hepato real damage, Skin rashes, pruritus and aplastic anemia 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.

Contraindications: Diclofenac Sodium is contraindicated in patients with history of Hypersensitivity, active peptic ulcer or Gastrointestinal bleeding, and those who are known to develop asthma, urticaria or other allergic reactions with aspirin or other NSAID's. Acute porphyria is a contraindication for Diclofenac.

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.

Precautions and Warning: Patients with a history of gastrointestinal disease, severe hepatic, cardiac or renal insufficiency. Patients on long term treatment with Diclofenac should have periodic blood counts.

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 initial treatment with diclofenac injection continues with diclofenac tablets or suppositories 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.

Use in Pregnancy: Because of the known effects of prostaglandin inhibiting drugs on the fetal cardiovascular system, use of diclofenac during late pregnancy should be avoided.
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.

Drug Interactions: Concomitant administration of aspirin lowers the plasma concentrations of diclofenac. Diclofenac may raise plasma concentrations of lithium or digoxin when administered together. On the other hand, it may reduce the activity of diuretics and anti-hypertensive.

Incompatibilities: None known

Dosage and Administration: IM dose of 75mg once daily. In severe condition, 75mg twice daily. In renal colic, a dose of 75mg repeated once after 30 minutes if necessary.

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 when initial treatment with diclofenac injection continues with diclofenac tablets or suppositories 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.

Storage condition: Keep in a cool place, protect from light.

Presentation: Carton of 100 ampoules.

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