



Diclofen[®]

Diclofenac Sodium BP

Description: Diclofenac Sodium is a non steroidal anti-inflammatory drug which has analgesic, antipyretic, anti-inflammatory actions.

Mode of action: Diclofenac selectively inhibits cyclo-oxygenase enzyme as a result it inhibits prostaglandin synthesis and shows anti-inflammatory, analgesic and antipyretic properties.

Pharmacokinetics: Diclofenac is well absorbed from GI tract after oral administration. About 60% of the oral dose reaches the systemic circulation. Peak plasma level achieved within 2 hours (range 1-4 hrs) after administration. Following a dose of 75 mg injection, peak plasma concentrations are reached within 10-22 minutes. 60% of administered dose is excreted via the kidneys. The mean elimination half-life is 1-2 hours.

Composition: Diclofen[®] 25 mg Tablet: Each enteric-coated tablet contains Diclofenac Sodium BP 25 mg.

Diclofen[®] 50 mg Tablet: Each enteric-coated tablet contains Diclofenac Sodium BP 50 mg.

Diclofen[®] SR 100 mg Tablet: Each film-coated tablet contains Diclofenac Sodium BP 100 mg.

Diclofen[®] 75 mg Injection: Each 3 ml ampoule contains Diclofenac Sodium BP 75 mg.

Diclofen[®] Plus IM Injection: Each 2 ml ampoule contains Diclofenac Sodium BP 75 mg and Lidocaine Hydrochloride USP 20 mg.

Diclofen[®] 12.5 mg Suppository: Each suppository contains Diclofenac Sodium BP 12.5 mg.

Diclofen[®] 25 mg Suppository: Each suppository contains Diclofenac Sodium BP 25 mg.

Diclofen[®] 50 mg Suppository: Each suppository contains Diclofenac Sodium BP 50 mg.

Diclofen[®] 100 mg Suppository: Each suppository contains Diclofenac Sodium BP 100 mg.

Indications: Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, pain following surgery and any other joint pain. Diclofenac gel is indicated for local treatment of traumatic inflammation of the tendons, ligaments, muscles and joints.

Dosage & administration: *Oral:* 75-150 mg daily in 2-3 divided doses.

IM: 75 mg once daily (twice daily in severe cases) for maximum of 2 days.

IV: 75 mg repeated if necessary after 4-6 hours for maximum of 2 days. Prevention of post-operative pain, initially after surgery 25-50 mg over 15-60 minutes then 5 mg/hour for maximum 2 days.

Suppository: 75-150 mg daily in divided doses.

Child 1-12 years: (Juvenile arthritis, by mouth or by rectum) 1-3 mg/kg daily in divided doses (25 mg and 12.5 mg tablet).

Contraindications: Patients with hypersensitivity to diclofenac, aspirin or any other NSAIDs, lidocaine etc. are contraindicated to use this drug. Patients with peptic ulcer and gastrointestinal bleeding are also contraindicated to use this drug.

Side effects: Diclofenac is well tolerated, but the common side effects are epigastric pain, nausea, headache, dizziness and diarrhoea.

Use in pregnancy & lactation: Diclofenac should not be used during pregnancy, USFDA pregnancy category D. Very small quantities of diclofenac may be detected in breast milk, but no undesirable effects on the infant are to be expected.

Precautions: Diclofenac should not be used in children for other reasons than juvenile rheumatoid arthritis. In renal, cardiac or hepatic impairment, it should be used with caution. It is better to avoid more than one oral NSAID at a time.

Drug interactions: Concomitant ingestion with acetylsalicylic acid lowers the plasma concentration of each other. Diclofenac increases the plasma concentrations of digoxin, methotrexate and antagonize the activity of diuretics.

Storage: Store in a cool and dry place, protected from light.

Packaging

Diclofen[®] 25 mg Tablet: Each carton contains 10X10 tablets in blister pack.

Diclofen[®] 50 mg Tablet: Each carton contains 10X10 tablets in blister pack.

Diclofen[®] SR 100 mg Tablet: Each carton contains 10X10 tablets in blister pack.

Diclofen[®] 75 mg Injection: Each carton contains 5X2 ampoules in blister pack.

Diclofen[®] Plus IM Injection: Each carton contains 3X5 ampoules in blister pack.

Diclofen[®] 12.5 mg Suppository: Each carton contains 5X5 suppositories in strip pack.

Diclofen[®] 25 mg Suppository: Each carton contains 5X2 suppositories in strip pack.

Diclofen[®] 50 mg Suppository: Each carton contains 5X5 suppositories in strip pack.

Diclofen[®] 100 mg Suppository: Each carton contains 5X2 suppositories in strip pack.