

Diclofen[®] Gel

Diclofenac Sodium

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

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

Pharmacokinetics: Diclofenac is well absorbed from skin after local administration of Diclofenac gel & 6% of total dose applied is absorbed. Maximum plasma concentration of Diclofenac gel is about 100 times lower than oral administration of Diclofenac. The mean elimination half-life is 1-2 hours. Peak plasma concentration is achieved within 6 $\frac{1}{2}$ hours.

Composition: Diclofen[®] Gel: Each gram contains Diclofenac Diethylamine BP 11.61 mg equivalent to Diclofenac Sodium 10 mg.

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

Dosage & administration: 6-8 gm daily in 3-4 divided dosage at least for 14 days. Before application of **Diclofen[®] Gel** the skin should be clean and dry. Apply the gel on site of inflammation, rubbing lightly on the skin surface until the gel disappears.

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. Do not apply on wound or torn skin surface. Do not use lotion and other cosmetics on the site after use of Diclofenac. Avoid exposure to sun and UV rays.

Drug interactions:

Concomitant ingestion with Aspirin lowers the plasma concentration of each other. Diclofenac increases the plasma concentrations of Digoxin, Methotrexate and antagonize the activity of diuretics.

Storage: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging:

Diclofen[®] Gel: Each carton contains a tube having 20 gm gel.