

ROFENAC®

Antirheumatic, anti-inflammatory, analgesic

Composition:

Sodium - (0-[(2,6-dichlorophenyl)-amino]-phenyl)-acetate (Diclofenac Sodium).
Rofenac is available as an enteric coated tablet of 25 mg, 50 mg, sustained release 100 mg tablet, for oral administration, and as an ampoule of 75 mg for intramuscular administration.

Properties:

Rofenac (Diclofenac) is a nonsteroidal compound with pronounced antirheumatic, anti-inflammatory, analgesic, and antipyretic properties. It inhibits prostaglandin biosynthesis which plays a major role in causing inflammation, pain and fever.

Pharmacokinetics:

Rofenac (Diclofenac) is rapidly and completely absorbed from the gastrointestinal tract when taken with or after meal. Peak plasma levels are reached within an average of 2 hours after a single oral dose of Rofenac tablet 50 mg. Rofenac SR Tablets are also completely absorbed from GIT. As the active substance is released slowly, peak plasma concentration is lower than those attained after administration of conventional dosage forms. The plasma half-life is 1 - 2 hours.

Rofenac is metabolized in the liver and the metabolites are excreted in the urine and the bile. No accumulation occurs provided the recommended dosage intervals are observed even in patients suffering from renal impairment.

Diclofenac reaches higher levels in the synovial fluid than in plasma and remain higher for up to 12 hours.

Indications:

Rofenac is indicated in the treatment of :

- Rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis.
- Non-articular rheumatism.
- Acute musculoskeletal disorders and back pain.
- Painful syndromes of the vertebral column.
- Relief of pain in acute trauma and fractures.
- Control of pain and inflammation in orthopedic, dental and other surgeries.
- Painful inflammatory conditions in gynaecology and primary dysmenorrhoea.
- Renal colic and biliary colic (Rofenac ampoules are recommended).
- Acute attacks of gout.

Dosage and Administration:

Tablets:

The dose of Rofenac should be adjusted to the patient's response and tolerance. The usual recommended dose is 100 - 150 mg daily in divided doses up to a maximum of 200 mg daily. The tablet should be swallowed whole with water or juice, preferably before meals. The dose of Rofenac SR tablet 100 mg is usually 1 tablet daily. If necessary the dosage can be increased to 150 mg daily by giving a tablet of 50 mg tab. in the morning.

Ampoules:

The dose is generally one ampoule daily administered by deep intramuscular injection. In severe cases (e.g. renal or biliary colic) two injections can be given daily. Alternatively, it is possible to combine one ampoule with the tablet form of Rofenac up to a maximum daily dose of 150 mg. Rofenac ampoules should not be given for more than 2 days, if necessary the treatment can be continued with Rofenac tablets.

Contraindications:

- Hypersensitivity to Diclofenac and to sulfite excipient in case of ampoule.
- Rofenac like other nonsteroidal anti-inflammatory drugs, should not be given to patients with peptic ulcer and to patients in whom aspirin induces asthma, acute rhinitis and urticaria.

Precautions:

Rofenac (Diclofenac) should be used with caution in patients with a history of cardiovascular disease as well as in patients suffering from severe impairment of hepatic function.

Owing to the importance of prostaglandins for maintaining renal blood flow, particular caution is called for

when using Rofenac in cases of impaired cardiac or renal function, in patients being treated with diuretics, and in those recovering from major surgical operations.

Like other non steroidal anti-inflammatory drugs, Rofenac (Diclofenac) may trigger allergic reactions including anaphylaxis even with patients receiving the product for the first time.

Rofenac (Diclofenac) should be used during pregnancy only if the benefits to the mother justify the potential risks to the fetus. Like other prostaglandin inhibiting drugs, use of Rofenac during late pregnancy should be avoided. Diclofenac passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected. Rofenac SR 100 mg tablet should not be broken or chewed. It should be swallowed with liquid and taken at mealtimes if possible, owing to high active substance content, Rofenac SR 100 mg tablet is not suitable for children.

Special Warnings :

Cardiovascular Risk:

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Diclofenac is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk:

NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Side Effects:

Rofenac (Diclofenac) is generally well tolerated. The most common side effects include gastro-intestinal disturbances, headache, and dizziness. Fluid retention, liver function disorders, rash and pruritis have been reported.

Interactions:

Various nonsteroidal anti-inflammatory agents are liable to inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, making it necessary to monitor these levels.

Patients taking diclofenac and are also receiving Digoxin, Methotrexate, Cyclosporine or lithium, should be observed for potential development of the specific toxicities of these drugs.

Concomitant administration of other systemic nonsteroidal anti-inflammatory agents or glucocorticoids may increase the occurrence of side effects.

Storage:

Store below 25°C.

Presentations:

Rofenac is available as 25mg tablets, 50mg tablets, 100mg tablets & 75mg/3ml ampoules.

This is a medication

- A medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medications out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Manufactured by **SPIMACO**
Al-Qassim Pharmaceutical Plant
Saudi Pharmaceutical Industries &
Medical Appliances Corporation
Saudi Arabia.

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