15 cm

18 cm

LF-0109

FENAC® INJECTION 25 MG/ML

Description : Clear colorless solution.

Composition :

Each mL contains :

(i) Active ingredient **Diclofenac Sodium 25 mg**
(ii) Preservative used **Benzyl Alcohol 20.0 mg**

Actions :

Antirheumatic, anti-inflammatory, analgesic, antipyretic.

Pharmacodynamics :

Diclofenac contains a non-steroidal compound with pronounced anti-rheumatic, anti-inflammatory, analgesic and antipyretic properties.

Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of action.

In rheumatic diseases, the anti-inflammatory and analgesic properties of Diclofenac elicit a clinical response characterized by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness and swelling.

Pharmacokinetics :

Diclofenac is absorbed from the gastro-intestinal tract but is subject to first pass metabolism. Approximately 20 minutes after IM injection of 75 mg of diclofenac, a mean peak plasma concentration of 2.5 µg/mL is attained. About half of the active substance is metabolized during its first passage through the liver.

Pharmacokinetics behavior remains unchanged following repeated administration. No accumulation occurs provided the recommended dosage intervals are observed. Diclofenac enters the synovial fluid, where maximum concentrations are measured 2-4 hours. After the peak plasma values have been attained .The apparent half-life for elimination from the synovial fluid is 3-6 hrs. Only 4-6 hours after administration, therefore the concentration of the active substance is higher in the synovial fluid than in the plasma and remain higher for 12 hours.

The remainder of the dose is eliminated in the form of metabolites mainly in the bile, urine and feces. The age of the patient has no influence on the absorption, metabolism, or excretion of diclofenac.

Indications :

Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondyarthritis. Non-articular rheumatism. Acute attacks of gout. Painful syndromes of vertebral column, post-traumatic and postoperative inflammation.

Route of Administration : Deep Intramuscular (IM)

Dosage And Administration :

Dosage :

For the symptomatic treatment of acute or chronic rheumatoid arthritis, the usual dosage of diclofenac sodium is 150-200 mg daily, administered in divided dosages. Exceeding 200 mg daily have not been established in patients with rheumatoid arthritis. For the symptomatic treatment of osteoarthritis, the usual dosage of diclofenac sodium is 100-150 mg daily, administered in divided doses of 75 mg twice daily or 50 mg 2 times daily. The safety and efficacy of dosages exceeding 150 mg daily have not been established in patients with osteoarthritis. For the symptomatic treatment of ankylosing spondylitis, the usual dosage of diclofenac sodium is 100-125 mg daily administered in divided doses of 25 mg 4 or 5 times daily. The safety and efficacy of dosage exceeding 125 mg daily have not been established in patients with ankylosing spondylitis.

After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

As a general recommendation, the dose should be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see section Warnings and Precautions).

Established Cardiovascular Disease Or Significant Cardiovascular Risk Factors

Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≦100 mg daily if treated for more than 4 weeks (see section Warnings and Precautions).

Side Effects / Adverse Reactions :

By far the most common adverse effects were gastro-intestinal symptoms, most of them minor, occurring in about 20 %. Gastro-intestinal symptoms were followed in frequency by central nervous system side effects such as headache (7%) and dizziness (3%).

Other side effects include heartburn, nausea, vomiting, bloating, stomach gas or pain, diarrhea, constipation, dark stools, nervousness, sleeplessness, depression, loss of appetite, fatigue, itching, rash or skin eruption, double or blurred vision, dry or irritated eyes, heart failure, palpitations, abnormal heart rhythms, anemia or other changes in the composition of the blood, changes in liver function, hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis (Lyell's Syndrome), photosensitivity reactions, tingling in the hands or feet, fever, enlarged breast, urinary tract irritation, thirst, frequent urination, swelling and appearance of black and blue marks.

Cardiac Disorders

Uncommon*: Myocardial infarction, cardiac failure, palpitations, chest pain.

* The frequency reflects data from long-term treatment with a high dose (150 mg/day).

Kounis syndrome : Frequency "not known"

Description Of Selected Adverse Drug Reactions

Arteriothrombotic Events

Meta-analysis and pharmacoepidemiological data point towards an 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 (see section Warnings and Precautions).

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.

Anticoagulants : While studies have not shown Diclofenac to interact with anticoagulants of the warfarin type, caution should be exercised, nonetheless, since interactions have been seen with other NSAIDs. Because prostaglandins play an important role in hemostatis, and NSAIDs affect platelet function as well, concurrent therapy with all NSAIDs, including Diclofenac and warfarin requires close monitoring of patients to be certain that no change in their anticoagulant dosage is required.

Digoxin, Methotrexate, Cyclosporine : Diclofenac, like other NSAIDs, may affect renal prostaglandin's and increase the toxicity of certain drugs. Ingestion of Diclofenac may increase serum concentrations of digoxin and methotrexate and increase cyclosporine's nephrotoxicity. Patients who begin taking digoxin, methotrexate, or cyclosporine may develop toxicity characteristics for these drugs. They should be observed closely, particularly if renal function is impaired. In the case of digoxin, serum levels should be monitored.

Lithium : Diclofenac decreases lithium renal clearance and increases lithium plasma levels. In patients taking Diclofenac and lithium concomitantly, lithium toxicity may develop.

Oral Hypoglycemics : Diclofenac does not alter glucose metabolism in normal subjects nor does it alter the effects of oral hypoglycemic agents. There are rare reports, however, from marketing experiences of changes in effects of insulin or oral hypoglycemic agents in the presence of Diclofenac that necessitated changes in the doses of such agents. Both hypo-and hyperglycemic effects have been reported. A direct causal relationship has not been established, but physicians should consider the possibility that Diclofenac may alter a diabetic patient's response to insulin or oral hypoglycemic agents. Diclofenac may alter a diabetic patient's response to insulin or oral hypoglycemic agents with potassium-sparing diuretics may be associated with increased serum potassium levels.

Other Drugs : In small groups of patients (7-10/interaction study), the concomitant administration of azathioprine, gold, chloroquine, D-penicillamine, prednisolone, doxycycline, or digitoxin did not significantly affect the peak levels and AUC values of Diclofenac.

Contraindications :

Fenac injection is contraindicated to patients with hypersensitivity to it. Fenac injection should not be given to patients in whom diclofenac, aspirin or other nonsteroidal anti-inflammatory drugs induce asthma, urticaria, or other allergic type reactions.

Severe cardiac failure (see section Warnings and Precautions).

Warnings and Precautions :

As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age.
Not to be used in neonates.

Gastrointestinal Effects

NSAIDs, including diclofenac, may be associated with increased risk of gastrointestinal anastomotic leak.

Close medical surveillance and caution are recommended when using diclofenac after gastrointestinal surgery.

Warnings :

RISK OR GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAID, even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Measures such as the use of physical therapy and mild analgesics like paracetamol (when inflammation is not a major factor) should be instituted prior to initiation of therapy either NSAIDs should only be used after proper appraisal of potential risks to patients. It should be used with lowest effective dose only as long as needed. This drug should not be co-administered with other NSAIDs. Prescribers should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur. In considering the use of relatively large doses (within the recommended dosage range), sufficient benefits should offset the potential increased risk of GI toxicity.

Cardiovascular Effects

Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, maybe associated with an increased risk of serious cardiovascular thrombotic events (including myocardial infarction and stroke).

Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≦100 mg daily when treatment continues for more than 4 weeks.

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 treatment continues for more than 4 weeks.

Patients should 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.

General Precautions : During prolonged treatment with Fenac, blood counts and monitoring of hepatic and renal function are indicated.

Severe cutaneous reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis (Lyell's Syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

Adverse effects : Dermatological: Occasional-rashes or skin eruptions Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Pregnancy and Lactation :

During pregnancy, particularly to the last 3 months, Fenac should be used only for compelling reasons and only in the lowest effective doses.

Overdose and Treatment :

Overdose symptoms : Manifestations include drowsiness, dizziness, confusion, disorientation, lethargy, tingling in the hands or feet, numbness, nausea, vomiting, upset stomach, pains, headache, ringing or buzzing in the ears, sweating and blurred vision.

Treatment : Supportive and symptomatic treatment should be given for complications, such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression.

Storage Conditions :

Store below 30°C. Protect from light. For vials after opening the flip-off, never open the rubber cap of the vial. The vial should be kept in the refrigerator at 2°C - 8°C for a period of not more than 48 hours after the withdrawal with sterile syringe to avoid the growth of micro-organism that might have contaminated during the withdrawal of the medicine. Some unfiltered air might be pumped into the sterile vial during the withdrawal.

Reg. No. MAL 19986419AZ

Shelf-life : 4 years

Pack size:

Ampoule : 1 box [10 ampoules of 3 mL] and 1 box [50 ampoules of 3 mL]

Vial : 1 box [10 vials of 10 mL/vial]

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