

CLOFENAC 50 TABLET

DESCRIPTION

Round, yellowish brown enteric coated tablet with shallow convex faces and bevel-edged.

COMPOSITION

Diclofenac sodium 50 mg per tablet

PHARMACODYNAMICS

Diclofenac sodium has analgesic, anti-inflammatory and anti-pyretic properties. It is an inhibitor of prostaglandin synthetase (cyclo-oxygenase).

PHARMACOKINETICS

- Absorption:** Diclofenac is absorbed form the gastro-intestinal tract but is subject to first-pass metabolism.
- Protein Binding:** At the therapeutic concentration, diclofenac is more than 99% bound to plasma proteins.
- Excretion:** Diclofenac is excreted primarily in the form of metabolites, mainly in the urine but also in the bile.

INDICATIONS

Diclofenac sodium is used for relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout and following some surgical procedures.

CONTRAINDICATIONS

- Diclofenac sodium was considered unsafe in patients with acute porphyria because it has been shown to be porphyrinogenic in animals or *in vitro* system.
- Avoid giving to patients who are sensitive to aspirin.
- Use in pregnant women should be avoided.
- Severe cardiac failure (see section WARNING and PRECAUTIONS)

WARNING

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 hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

Cardiovascular effects

Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, may be 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 ≤ 100mg 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.

RISK OF GASTROINTESTINAL 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 NSAIDs even in the absence of previous GI tract symptoms.

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.

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, 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.

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PRECAUTIONS

Diclofenac should be given with care to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, peptic ulceration, renal failure and in those who are receiving coumarin anticoagulants.

MAIN SIDE/ADVERSE EFFECTS

Cardiac disorders:

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

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.

Frequency "not known": Kounis syndrome

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

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 (150mg daily) and during long-term treatment (see section WARNING AND PRECAUTIONS).

The most common side effects occurring with diclofenac sodium are gastrointestinal disturbances. Peptic ulceration and intestinal bleeding have been reported. Other side effects include headache, dizziness, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision and other ocular reactions.

DRUG INTERACTIONS

Avoid concomitant use with triamterene.

OVERDOSAGE

Symptoms : Headache, nausea, gastrointestinal bleeding.

Treatment : Emesis or gastric lavage, if appropriate.

Symptomatic and supportive measures.

DOSAGE AND ADMINISTRATION

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 WARNING 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 ≤ 100mg daily if treated for more than 4 weeks (see section WARNING AND PRECAUTIONS)

Adult

Oral, 75 to 150 mg daily in divided doses.

Children

For juvenile chronic arthritis - Oral, 1 to 3 mg per kg body weight in daily divided doses.

The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 30°C. Protect from moisture.

Presentation/Packing: Blisters of 10 x 10's

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