Zolfin®

Tablet

Description

Zolfin contains Aceclofenac which is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of Aceclofenac is largely based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

Indications

Zolfin is indicated for the relief of pain and inflammation in both acute and chronic conditions like osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, dental pain, gynaecological pain, low back pain etc.

Dosage and Administration

Adults : The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Children : There are no clinical data on the use of Aceclofenac in children.

Elderly : The pharmacokientics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.

Renal insufficiency : There is no evidence that the dosage of Aceclofenac needs to be modified in patients with mild renal impairment, but as with other NSAIDs caution should be exercised.

Hepatic insufficiency : There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100 mg be used.

Contraindications

Zolfin should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding, and in patients with moderate to severe renal impairment. It should not be prescribed during pregnancy,

unless there are compelling reasons for doing so. In this situation the lowest effective dosage should be used. Aceclofenac should not be administered to patients hypersensitive to the drug or in whom aspirin or NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria.

Precautions

Renal : Patients with mild renal or cardiac impairment and the elderly should be kept under surveillance, since the use of NSAIDs may result in deterioration of renal function. In these situations the lowest effective dose should be used and renal function be monitored regularly. *Hepatic :* If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Aceclofenac should be discontinued. Use of Aceclofenac in patients with hepatic porphyria may trigger an attack. *Haematological :* Aceclofenac may reversibly inhibit platelet aggregation.

Drug Interactions

Lithium and Digoxin : Like many NSAIDs, Aceclofenac may increase plasma concentrations of Lithium and Digoxin.

Diuretics : like other NSAIDs, it may inhibit the activity of diuretics.

Anticoagulants : Like other NSAIDs, it may enhance the activity of anticoagulants.

Antidiabetic agents : There have been isolated reports of hypoglycaemic and hyperglycaemic effects if the drugs are used concomitently.

Methotrexate : NSAIDs may increase methotrexate plasma levels, resulting in increased toxicity.

Other NSAIDs and Steroids : Concomitant therapy with Aspirin, other NSAIDs and steroids may increase the frequency of side effects.

Cyclosporin : Cyclosporin nephrotoxicity may be increased by the effect of NSAIDs on renal prostaglandins.

Quinolone antmicrobials : Convulsions may occur due to an interaction between quinolones and NSAIDs.

Side Effects

The majority of side effects observed have been reversible and of minor in nature and include gastrointestinal disorders (dyspepsia, abdominal pain, nausea and diarrhoea) and occasional occurrence of dizziness. Dermatological complaints including pruritus and rash, abnormal hepatic enzyme and raised serum creatinine levels have occasionally been reported.

Use in Special Populations

Pregnancy : There is no information on the use of Aceclofenac during pregnancy. Aceclofenac should not be prescribed during pregnancy, unless there are compelling reasons for doing so.

Lactation : There is no information on the secretion of Aceclofenac to breast milk. The use of Aceclofenac should be avoided in lactation unless the potential benefits to the mother outweigh the possible risks to the foetus.

Commercial Pack

Zolfin® Tablet: Box containing 100 film coated tablets in 10 x 10's blister strips. Each film coated tablet contains Aceclofenac BP 100 mg.