Celofen®

Aceclofenac

Presentation
Celofen® 100mg Tablets: Round, light pink colored film coated tablet, one side embossed with 'ACI' and other side with a break line. Each tablet contains 100mg Aceclofenac BP.

Description
Celofen® is a non-steroidal agent with anti-inflammatory and analgesic properties. Its mechanism of action is largely based on inhibition of prostaglandin synthesis. Celofen® is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

Indications & uses
Celofen® is indicated in relieving pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Dosage & administration
Adults: The maximum recommended dose is 200mg daily, taken as two separate 100mg doses, one tablet in the morning and one in the evening.
Children: There is no clinical data on the use of Aceclofenac in children.
Elderly: The pharmacokinetics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose and dose frequency.
Renal insufficiency: There is no evidence that the dosage of Aceclofenac needs to be modified in patients with mild renal impairment.
Hepatic insufficiency: The dose of Aceclofenac should be reduced in patients with hepatic impairment. An initial daily dose of 100mg should be administered.

Contraindications, warnings, etc.
Contraindications: Aceclofenac is contraindicated in patients previously sensitive to Aceclofenac or aspirin or other NSAIDs. It should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding and moderate to severe renal impairment.
Precautions: Aceclofenac should be administered with caution to patients with symptoms indicative of gastrointestinal disorders, with a history of peptic ulceration, ulcerative colitis, Crohn's disease, hepatic porphyria, and coagulation disorders. Patients suffering from severe hepatic impairment must be monitored.
Side effects: Generally Aceclofenac is well tolerated. The majority of side effects observed have been reversible and of a minor nature and include gastrointestinal disorders (dyspepsia, abdominal pain, nausea and diarrhea) and occasional occurrence of dizziness. Dermatological side effects include pruritus and rash. Abdominal hepatic enzyme levels and raised serum creatinine have occasionally been reported.
Use in pregnancy & lactation: Pregnancy: There is no information on the use of Aceclofenac during pregnancy. Aceclofenac should not be administered during pregnancy, unless there are compelling reasons for doing so. The lowest effective dose should be administered. Lactation: It is not known whether Aceclofenac is excreted in human milk or not. Therefore, Aceclofenac should not be given to lactating mother unless potential benefits outweigh the risk to the fetus.

Drug interactions: Lithium and Digoxin: Aceclofenac, like other NSAIDs, may increase plasma concentrations of lithium and digoxin. Diuretics: Aceclofenac, like other NSAIDs, may inhibit the activity of diuretics. Anticoagulants: Like other NSAIDs, Aceclofenac may enhance the activity of anticoagulants. Quinolones: Convulsion may occur due to an interaction between quinolones and NSAIDs. Other NSAIDs and steroids: Concomitant therapy with aspirin, other NSAIDs and steroids may increase the frequency of side effects.

Overdose: There is no human data available on the consequences of Aceclofenac overdosage. The symptoms could be: nausea, vomiting, stomach pain, dizziness, somnolence and headache. Treatment: If required, gastric lavage, charcoal in repeated doses. Antacids when necessary and other symptomatic treatment should be given for complications.

Pharmaceutical precautions
Store in a cool dry place, protect from light.

Package quantities
Celofen®100mg Tablets: Carton of 50 tablets in Alu-PVC blister.

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ACI Limited
Narayanganj, Bangladesh