Aceclofar

Anti-inflammatory, Analgesic Tablets

Composition

Each tablet contains:

Active ingredient: Aceclofenac 100mg

Excipients: Lactose, starch, povidone, croscarmellose, magnesium stearate, hypromellose, titanium dioxide, talc, and polyethylene glycol.

Properties

Aceclofar is a non-steroidal anti-inflammatory drug (NSAID) of phenylacetic acid type that is structurally related to diclofenac. Aceclofenac has potent analgesic, anti-inflammatory, and antipyretic effects. Its mechanism of action is based largely on the inhibition of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins processes. Aceclofenac is absorbed rapidly as unchanged drug when taken orally, and its analgesic effect can begin within 30 minutes of ingestion. It reaches peak plasma concentration 1 to 3 hours after ingestion. A dose of 100mg is 100% bioavailable, C_{max}, T_{max} and AUC increase in a dose-proportional (50-150mg) manner. The mean plasma elimination half-life is approximately 4 hours, and the parent compound and its metabolites are eliminated primarily in the urine and, to a lesser extent, in the feces.

Aceclofenac is metabolized into a large number of compounds. The most important metabolite is H-aceclofenac (4-hydroxyaceclofenac), diclofenac accounts for <1% of the activity and for 4-7% of drug recovered from the urine. These metabolites are excreted by the kidneys in their conjugated forms.

Aceclofenac has been detected in synovial fluid within 1 hour after dosage, at levels corresponding to 57% of the levels detected in plasma.

When aceclofenac was given in repeated doses, no accumulation was observed in humans. Plasma protein binding of aceclofenac is approximately 99%.

When aceclofenac was administered to fasting and fed healthy volunteers, only the rate and not the extent of aceclofenac absorption was affected by the presence of food in the gastrointestinal tract.

Indications

Aceclofar is indicated for the acute and chronic treatment of the signs and symptom of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and scapulohumeral periarthritis. It is also indicated for pain of various etiologies such as musculoskeletal pain (e.g. low back pain), dental pain, or postsurgical pain (e.g., post-episiotomy, post-tooth extraction).

Dosage

The usual dose is 100mg every 12 hours. The dosage regimen should be individualized according to the indication and other clinical variables.

Elderly Patients: Limited pharmacokinetic data, as well as clinical experience, suggest that the dose for the elderly should be the same as that in younger patients.

Hepatic Insufficiency: Patients with mild hepatic impairment should receive an initial daily dose of 50mg every 12 hours.

If you miss a dose

- Take the missed dose as soon as possible.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications

It is contraindicated in patients with known hypersensitivity to aceclofenac or to any of the inactive ingredients. Aceclofenac should not be administered to patients who are hypersensitive to diclofenac.

Severe and sometimes fatal anaphylactic-like reactions have been reported in patients on NSAIDs.

As with other NSAIDs, aceclofenac is contraindicated in patients who have experienced bronchospasm, urticaria or acute rhinitis while taking acetylsalicylic acid or other NASAIDs, because of the risk of severe allergic-type reactions.

Aceclofenac should not be used in patients with porphyria or active peptic ulcer.

This product is contraindicated during pregnancy and lactation.

Precautions

Gastrointestinal Effects: As with other NSAIDs, aceclofenac can produce gastrointestinal irritation, i.e., gastritis, duodenitis, or peptic ulcer. Therefore, it is recommended that aceclofenac should not be given to patients who actively demonstrate gastrointestinal pathology of an irritative nature. NSAIDs have caused gastrointestinal bleeding that has resulted in hospitalization or even death, sometimes without previous warning symptoms. Therefore, patients should be maintained on the lowest dose of aceclofenac consistent with achieving a satisfactory therapeutic response.

Fluid Retention and Edema: Fluid retention and edema have been reported in some patients taking aceclofenac and other NSAIDs. Therefore, it should be used with caution in patients with a history of cardiac decompensation, severe hypertension, or other conditions predisposing to fluid retention.

Renal Impairment: As with other NSAIDs, it is advised to use the lowest effective dose for patients suffering from mild renal impairment and renal function should be monitored. In case of moderate to severe impairment, it is better to avoid the use of NSAIDs unless the benefits outweight the possible risks.

Hepatic Insufficiency: Caution is advised for patients with hepatic insufficiency as NSAIDs may increase the risk of gastrointestinal bleeding and may cause fluid rentention. It is better to avoid the use of NSAIDs in patients suffering from severe hepatic impairment.

Children: Safety and effectiveness in children under 12 years old have not be established.

Elderly: As with other NSAIDs, caution should be exercised in the trearment of elderly patients.

Patients suffering from dizziness, vertigo or other CNS disorders should refrain from taking NSAIDs while driving or operating dangerous equipment until it is known how a particular drug affects them.

This medication should be taken only as directed by a physician.

Side Effects

The majority of adverse effects observed in patients taking aceclofenac have been reversible and of a mild nature. The following adverse events were reported frequently in some patients: dyspepsia, abdominal pain, nausea and diarrhea, flatulence, dizziness, headache, pruritus, rash, anemia, thrombocytopenia, and increased BUN and hepatic enzymes.

Overdosage

Since there is no specific antidote, treatment of aceclofenac overdose should be symptomatic.

Absorption should be minimized by gastric lavage and treatment with activated charcoal. Forced diuresis, dialysis or hemoperfusion are probably not useful in eliminating NSAIDs because of the high rate of protein binding and extensive metabolism.

Drug Interactions

NSAIDs may enhance the activity of lithium and digoxin by reducing plasma clearance. This property may be of clinical importance in patients with compromised cardiac function or hypertension. Blood pressure control in patients taking beta-blockers, ACE-inhibitors and diuretics should be carefully monitored in patients taking NSAIDs concurrently.

Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

Administration of NSAIDs with anticoagulants requires close monitoring and may require dose adjustment of the anticoagulant agent, which can be displaced from plasma proteins by NSAIDs.

Administration of NSAIDs with aspirin is not recommended because concomitant therapy may increase the frequency of side effects, possibly because of decreased binding sites for the NSAIDs.

Clinical studies have shown a structurally similar NSAID, diclofenac, which can be given together with oral diabetic agents without influencing the clinical effect, however, there have been isolated reports of hyperglycemia and hypoglycemia in patients taking aceclofenac. Therefore, consideration should be given to adjusting the dosage of hypoglycemic agents.

Caution should be exercised if NSAIDs and methotrexate are administered within 24 hours of each other, since NSAIDs may reduce the renal excretion of methotrexate levels, resulting in increased toxcity. NSAIDs may also increase the potential toxicity of cyclosporine.

Presentation

Aceclofar tablets: Pack of 10 tablets.

* *Store at a temperature of 15-25°C.*

THIS IS A MEDICAMENT

- **Medicament 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 medicament.**
- **The doctor and the pharmacist are experts in medicines their 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 all medicaments out of reach of the children**

Council of Arab Health Ministers, Union of Arab Pharmacists

***Any information? Call Our Toll Free No.* (971) 800-4994**

julphar

Produced by: julphar
Gulf Pharmaceutical Industries,
Ras Al Khaimah, U. A. E.