Alitra

(Aceclofenac) 100mg Tablets

الیٹرا

(ایسیکلوفینک) ۱۰۰ ملی گرام ٹیبلیٹس

COMPOSITION:
Each film coated tablet contains:
Aceclofenac (B.P.) 100mg

PHARMACOLOGY:
Alitra (Aceclofenac) is a non-steroidal agent with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cyclooxygenase which is involved in the production of prostaglandins.

Pharmacokinetics:
After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3 hours following ingestion. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%). Aceclofenac circulates mainly as unchanged drug, 4'-hydroxy aceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

Pharmacodynamics:
Aceclofenac has multi-factor mechanism of action. Outside the inflammatory cell, aceclofenac is metabolized to 4'-hydroxy aceclofenac. The parent drug and the metabolite penetrate the inflammatory cells and then hydrolyzed to the active metabolites diclofenac and 4'-hydroxy diclofenac, which inhibit IL-1 and TNF released by the inflammatory cells and therefore suppress production of PGE2 at the site of inflammation. Aceclofenac prevents neutrophil adhesion and accumulation at the inflammatory site in the early phase and thus blocks the pro-inflammatory actions of neutrophils.

INDICATIONS
Alitra is indicated for the relief of pain and inflammation in both acute and chronic pain like osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, dental pain, post-traumatic pain, low back pain, gynaecological pain etc.

DOSAGE AND 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.

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 diarrhoea) and occasional occurance of dizziness. Dermatological side effects including pruritus and rash. Abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

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.

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.

USE IN PREGNANCY AND 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: There is no information on the secretion of aceclofenac in breast milk. The use of aceclofenac should therefore be avoided during lactation unless the potential benefits to the mother outweigh the possible risks to the children.

OVERDOSE
There is no human data available on the consequences of aceclofenac overdosage. After overdosage, following therapeutic measures to be taken: absorption should be prevented as soon as possible by means of gastric lavage and treatment with activated charcoal. Supportive and symptomatic treatment should be given for complications.

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 hypoglycemic and hyperglycemic effects if the drugs are used concomitantly.
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 antimicrobials : Convulsions may occur due to an interaction between quinolones and NSAIDs.

STABILITY
See expiry on the pack.

INSTRUCTIONS
Store at room temperature (15-25°C). Protect from moisture & sunlight. Keep out of the reach of children. To be sold on prescription of a registered medical practitioner only.

PRESENTATION
Alitra 100mg Tablets: Box containing 30 film coated tablets in 3X10's Alu Alu blister strips.

ہدایات: دوا کو (15-25°C) درجہ حرارت پر نمی اور دھوپ سے محفوظ رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ دوا صرف مستند ڈاکٹر کے نسخہ پر ہی فروخت کی جائے۔

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