ACECLOFENAC
PARACETAMOL

Rx

ACF-PLUS

100 mg/500 mg Film-Coated Tablet
Non-Steroidal Anti-inflammatory and Antirheumatic / Analgesic

FORMULATION:
Each film-coated tablet contains:
Aceclofenac.....100 mg
Paracetamol.....500 mg

PRODUCT DESCRIPTION:
Orange coloured capsule shaped biconvex film coated tablet with break line on one side and other side plain.

PHARMACODYNAMICS:
Aceclofenac is a phenylacetic acid derivative that inhibits synthesis of the inflammatory cytokines interleukin-1b and tumour necrosis factor, and inhibits prostaglandin E2 production. It increases glycosaminoglycans (GAG) synthesis, the principal macromolecule of the extracellular matrix, which aids in repair and regeneration of articular cartilage. Thus, aceclofenac has positive effects on cartilage anabolism combined with modulating effect of matrix catabolism. Paracetamol has analgesic and antipyretic action with weak anti-inflammatory activity. It produces analgesia by increasing pain threshold and antipyresis by acting on the hypothalamic heat-regulating centre.

PHARMACOKINETICS:
Absorption: Aceclofenac: Rapidly absorbed; almost 100% bioavailability; peak plasma levels reached about 1.25-3 hr after oral admin.
Distribution: Aceclofenac: >99.7% bound to plasma proteins; distributes into synovial fluid.
Paracetamol: Distributes throughout most fluids of the body.
Metabolism: Aceclofenac: Probably metabolised by CYP2C9; average plasma elimination half- life: 4-4.3 hr.
Paracetamol: Mainly metabolised hepatically; plasma elimination half-life: 1-4 hr.
Excretion: Aceclofenac: About two-thirds of the administered dose is removed in the urine, mainly as conjugated hydroxymetabolites.

INDICATIONS:
Aceclofenac + Paracetamol is indicated for relief from pain and inflammation associated with ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis.

DOSAGE & ADMINISTRATION:
The usual dose is 2 tablets a day. Reduced dose should be used in patients with hepatic impairment.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Aceclofenac + Paracetamol is contraindicated in the following situations:
- Patients sensitive to Aceclofenac, Paracetamol or to any of the excipients of the product.
- Patients in whom aspirin or other Non-Steroidal Anti-Inflammatory Drug, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to drugs.
- Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleeding disorders.
- Patients with severe heart failure, hypertension, hepatic or renal insufficiency.
- Third trimester of pregnancy

WARNINGS AND PRECAUTIONS:
The combination of Aceclofenac and Paracetamol may cause dizziness. Driving or operating machinery should be avoided. Individuals receiving long term treatment should be regularly monitored for renal function tests, liver function test and blood count. It is used with caution in hepatic porphyria, coagulation disorder, history of peptic ulcer, ulcerative colitis, Crohn's disease cerebrovascular bleeding, pregnancy and lactation. Caution should be exercised in patients with mild to moderate impairment of cardiac, hepatic or renal function and in elderly patients who are more likely to be suffering from these conditions. Caution is also required in patients on diuretic therapy or otherwise at risk of hypovolemia.

PREGNANCY AND LACTATION:
Aceclofenac + Paracetamol (ACF-PLUS) should not be taken during pregnancy (Third trimester) and lactation.

ADVERSE DRUG REACTIONS:
Hypersensitivity, Leukocytoclastic vasculitis, a type III hypersensitivity reaction, has been reported after therapy with aceclofenac. Anaphylaxis has also occurred. Paracetamol are rare and usually mild, although haematological reactions including thrombocytopenia, leukopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Skin rashes and other hypersensitivity reactions occur occasionally.

DRUG INTERACTIONS:
Paracetamol: Reduced absorption of cholestyramine within 1 hr of administration.Accelerated absorption with metoclopramide. Aceclofenac: May increase the plasma concentrations of lithium and digoxin. Increased nephrotoxicity with diuretics. Serum-potassium should be monitored when used with potassium-sparing diuretics. May enhance activity of anticoagulants. May increase plasma methotrexate levels leading to toxicity if administered within 2-4 hours of methotrexate administration. Risk of convulsions with quinolones.
Potentially fatal. Paracetamol: Increased risk of liver damage in chronic alcoholics. Increased risk of toxicity with high doses or long term administration of barbiturates, carbamazepine, hydantoins, isoniazid, rifampicin and sulfinpyrazone.

OVERDOSE AND TREATMENT:
Overdosage may cause nausea, vomiting, pain in abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure. Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA:www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

Keep all medicines out of reach of children.

AVAILABILITY:
Alu/Clear PVC Blister Pack x 10's (Box of 100's)

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