

DESCRIPTION:

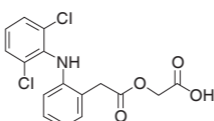
Actavis (Aceclofenac) tablet is a non-steroidal anti-inflammatory drug (NSAIDs) analog of Diclofenac. Aceclofenac is a medicine which is used in ankylosing spondylitis, osteoarthritis and rheumatoid arthritis.

Molecular Formula: C₁₆H₁₃Cl₂NO₄

Molecular Weight: 354.18472 g/mol

Chemical name: Glycolic acid, [o-(2,6-dichloroanilino)phenyl]acetate (ester)

Chemical Structure:



QUALITATIVE & QUANTITATIVE COMPOSITION:

Each film-coated tablet contains:

Aceclofenac BP.....100mg

Genix Specs.

MECHANISM OF ACTION: Actavis Tablets works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins are released at the sites of injury, tissue damage and immune reactions. Prostaglandins play an important role in both the inflammatory response of the body and stimulating the re-absorption of bone in diseases.

INDICATIONS AND USAGE: Actavis Tablet is used to relieve pain and inflammation in patients suffering from arthritis of the joints (osteoarthritis). This commonly occurs in patients over the age of 50 and causes the loss of the cartilage and bone tissue next to the joint. Autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis). arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

Pharmacokinetics: After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%). Aceclofenac circulates mainly as unchanged drug. 4'-hydroxyaceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites. No changes in the

pharmacokinetics of aceclofenac have been detected in the elderly.

DOSAGE & 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.

Pediatric population: Actavis Tablet is not recommended for use in children under 18 years of age.

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.

Pregnancy and lactation: Use Aceclofenac unless the potential benefit outweighs the risk. It should be avoided during the third trimester because it is associated with a risk of closure of fetal ductus. In addition, the onset of labour may be delayed and its duration may be increased. Actavis should be used with caution during breast-feeding.

Contraindications: It is contraindicated in recurrent peptic ulcer/hemorrhage. Actavis is contraindicated in patients who have previously shown hypersensitivity reactions (eg. Asthma, rhinitis, angioedema or urticaria). Severe heart failure, hepatic failure and renal failure.

Adverse Reactions : Gastro-intestinal disturbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur. Systemic as well as local effects of NSAIDs contribute to gastrointestinal damage; taking oral formulations with milk or food, or using enteric-coated formulations, or changing the route of administration may only partially reduce symptoms such as dyspepsia.

Drug Interactions : Aceclofenac may interact with lithium, cardiac glycosides, antihypertensives, quinolone antibiotics, diuretics, anticoagulants (warfarin & heparin), methotrexate, mifepristone, steroids (oestrogens, androgens, or glucocorticoids), cyclosporine or tacrolimus. Actavis Tablet must be taken preferably with or after food.

INSTRUCTIONS:

Store below 30°C.

Protect from heat, light & moisture.

Keep all medicines out of the reach of children.

PRESENTATION:

Actavis (Aceclofenac) Tablets 100mg are available in ALU/PVC blister pack of 1x10's.

For detailed information please contact:

GENIX

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