

Tekna[®]

Aceclofenac

COMPOSITION:

Tekna[®] 100 Tablet: Each film-coated tablet contains Aceclofenac BP 100 mg.

PHARMACOLOGY:

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 prostaglandin. It also stimulates cartilage matrix synthesis.

INDICATION:

For the relief of pain and inflammation in Osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

DOSE & ADMINISTRATION:

Adults: The recommended dose is 100 mg twice daily.

Children: No clinical data on the use of Aceclofenac in children is available.

Elderly: The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore it is not considered necessary to modify the doses frequency.

CONTRA-INDICATION:

Aceclofenac should not be administered to patients previously sensitive to Aceclofenac or in whom NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria or who are hypersensitive to this drug.

WARNING AND PRECAUTION:

Aceclofenac should be administered with caution to patients with symptoms indicative of gastrointestinal disorders, with a history of peptic ulcerating, ulcerative colitis, Crohn's disease, hepatic porphyria, and coagulation disorders.

SIDE EFFECTS:

The majority of side effects observed have been reversible and not a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea and diarrhea) and occasional occurrence of dizziness. Dermatological complaints including pruritus, rash and abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

USE IN PREGNANCY & LACTATION:

There is no information on the use of Aceclofenac during pregnancy. The regular use of NSAIDs during the last trimester of pregnancy may increase uterine tone and contraction. There is no information on the secretion of Aceclofenac to breast milk. The use of Aceclofenac should therefore be avoided in pregnancy and lactation unless the potential benefits to the mother out weight the possible risks to the fetus.

USE IN CHILDREN & ADOLESCENTS:

Aceclofenac tablet is not recommended for use in children and adolescents.

DRUG INTERACTION:

Lithium and Digoxin: Aceclofenac, like many NSAIDs may increase plasma concentration of Lithium and Digoxin.

Diuretics: Aceclofenac, like other NSAIDs may interact the activity of diuretics.

Anticoagulants: Like other NSAIDs, Aceclofenac may enhance the activity of anticoagulant. Close monitoring of patients on combined anticoagulants and Aceclofenac therapy should be under taken.

Methotrexate: Caution should be exercised if NSAIDs and Methotrexate are administered within 24 hours of each other, since NSAIDs may increase Methotrexate plasma levels, resulting in increased toxicity.

OVERDOSE:

There are no human data available on the consequences of aceclofenac overdosage. If overdosage is observed, therapeutic measures should be taken according to symptoms. Supportive and symptomatic treatment should be given for complications such as hypotension, gastro-intestinal irritation, respiratory depression and convulsions.

STORAGE:

Store in a dry and cool place below 30⁰ C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Tekna[®] 100 Tablet: Each box contains 5 x 10's tablets in blister strip.



Manufactured by

Team Pharmaceuticals Ltd.

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