

#### Aceclofenac

# Composition

Each film coated tablet contains Aceclofenac BP 100 mg.

#### Pharmacololov

Apitac<sup>®</sup> (Aceclofenac) is a non-steroidal agent with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cyclooxygenase, which is responsible for the production of prostaglandin. After oral administration, Aceclofenac is rapidly and completely absorbed as unchanged drug.

### Indications

For the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, dental pain, post-traumatic pain, low back pain, gynecological pain etc.

# **Dosage and Administration**

Route of administration: Oral.

Adults: The recommended dose is 100 mg (1 tablet), twice daily.

Children: There are no clinical data on the use of Aceclofenac in children.

 $\textbf{Elderly}: \textbf{The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore$ 

it is not considered necessary to modify the dose or dose frequency.

OR AS DIRECTED BY THE PHYSICIAN.

#### Contraindications

Aceclofenac should not be administered to patients with active or suspected peptic ulcer or gastro-intestinal bleeding. It should not be given to patients with moderate to severe renal impairment. Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function. It should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. Aceclofenac should not be administered to patients previously sensitive to Aceclofenac or in whom aspirin or NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria or who are hypersensitive to these drugs.

#### Warning & Precaution

### **Side Effects**

**Common side effects:** The majority of side-effects observed have been reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea and diarrhea) and occasional occurrence of dizziness.

Rate side effects: Dermatological complaints including pruritus and rash, abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

# Use in Pregnancy & Lactation

The use of Aceclofenac should be avoided in pregnancy and lactation unless the potential benefits to the mother outweigh the possible risks to the fetus.

# Use in Children & Adolescents

## **Drug Interactions**

Aceclofenac may interact with lithium, digoxin, diuretics, anticoagulants and methotrexate

## Overdose

## Storage

Store below  $30^{\circ}$  C temperature & dry place protected from light. Keep all medicines out of reach of children.

### Packing

Each box contains 10 x 10 tablets in blister strips.

\* Further information is available on request.

