



Aceflex®

Aceclofenac BP

Insert for prescribing information

Composition

Aceflex® 100 mg Tablet: Each film-coated tablet contains Aceclofenac BP 100 mg.

Description

Aceflex® (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. Peak plasma concentrations are reached approximately 1.25 to 3 hrs following ingestion.

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

- Adults: The recommended dose is 100 mg (1 tablet), twice daily, one in the morning and one in the evening.
- Children: There are no clinical data on the use of Aceclofenac in children.
- Elderly: The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.

Contraindication

Aceclofenac should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding. It should not be given to patients with moderate to severe renal impairment.

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.

Adverse Reactions

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 occurrence of dizziness. Dermatological complaints 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.

Use in Pregnancy & 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.

Drug-interactions

Lithium and digoxin: Aceclofenac like many NSAIDs, may increase plasma concentrations of lithium and digoxin.

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

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

Storage

Store at temperature not exceeding 30° C in a dry place. Protect from light.

Commercial Pack

Aceflex® 100 mg Tablet: Each box contains 5X10's tablets in Alu-PVC blister strips.

For child safety: Keeping medicines out of reach



MAKS

Manufactured for

Maks Drug Limited

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