

Contraindications

Fixonac[®] (Aceclofenac) is Contraindicated in the following situations:

- Patients Previously sensitive to Aceclofenac or Aspirin or other NSAID s
- Patients with active or suspected peptic or duodenal ulcer or who have GI or other bleeding disorders.
- In severe heart failure and renal or hepatic insufficiency.
- During last three months of pregnancy.

Precautions

Fixonac[®] (Aceclofenac) should be used with caution in patients suffering from GI disease and history of peptic ulceration, cerebrovascular bleeding, ulcerative colitis or coagulation disorders.

Caution should be taken in patients with mild to moderate renal, hepatic or cardiac function. Caution is also required with patients on diuretic.

Drug Interactions

Fixonac (Aceclofenac) is metabolized through cytochrome P4502C9 and a risk of pharmacokinetic interaction is therefore, possible with Phenytoin, Digoxin, Cimetidine, Tolbutamide, There is also a risk of pharmacokinetic interactions with drugs eliminated by active renal secretion such as Methotrexate and Lithium.

Use in Pregnancy and Lactation

There is no information of the use of Aceclofenac during pregnancy and lactation, The use of **Fixonac**[®] (Aceclofenac) should, therefore, be avoided during pregnancy and lactation unless the potential benefits to the mother outweigh the possible risks.

Storage

Store in a cool and dry place, away from light.

Commercial Pack

Box containing 10 x 10 Tablets in blister pack.



Manufactured by
EURO Pharma Ltd.
In Pursuit of Excellence
Dhaka, Bangladesh

©Regd. Trademark

Fixonac[®]

Aceclofenac BP 100 mg

Description

Fixonac[®] (Aceclofenac) is a phenyl acetic acid derivative and related to diclofenac, developed with the aim of producing a NSAID with an improved safety profile.

Composition

Each Tablet contains Aceclofenac BP 100 mg.

Mode of Action

Fixonac[®] (Aceclofenac) acts primarily by inhibiting prostaglandin synthesis. Aceclofenac is a potent inhibitor of cyclooxygenase, which is involved in the production of prostaglandin.

Pharmacokinetics:

Fixonac[®] (Aceclofenac) is well absorbed from the gastrointestinal tract; peak plasma concentration is reached 1-3 hours after an oral dose. Plasma elimination half-life is about 4 hours.

Indications

Fixonac[®] (Aceclofenac) is indicated for the symptomatic treatment of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and primary dysmenorrhoea.

Dosage and Administration

The maximum recommended dose is 200 mg daily in two divided doses. Reduction of dose is not necessary in case of elderly.

In renal failure: Dose adjustment is not necessary in mild renal insufficiency.

In hepatic failure: Dose should be decreased in patients with moderate to severe liver malfunction. The recommended initial daily dose is 100 mg in that case.

Side Effects

The Major side effects are gastrointestinal like dyspepsia abdominal pain, nausea, and diarrhea. Flatulence, gastritis, constipation, vomiting etc may also occur.