FREEMAX™

Aceclofenac BP 100 mg

Composition:

FREEMAX™ Tablet: Each film coated tablet contains Aceclofenac BP 100mg.

Description:

FREEMAX™ (Aceclofenac) is a nonsteroidal agent with marked antiinflammatory and analgesic properties.

The mode of action of ***FREEMAX***™ is largely based on the inhibition of prostaglandin synthesis. ***FREEMAX***™ is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

Pharmacokinetics:

After oral administration, ***FREEMAX***™ is rapidly and completely absorbed as an unchanged drug. Peak plasma concentrations are reached approximately $1^1/_4$ to 3 hrs following ingestion. ***FREEMAX***™ penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma.

The mean plasma elimination half-life is around 4 hrs. ***FREEMAX***™ is highly protein bound (> 99%). ***FREEMAX***™ circulates mainly as an unchanged drug. 4'-Hydroxyaceclofenac is the main metabolite detected in plasma. Approximately 2/3 of the administered dose is excreted in urine, mainly as hydroxymetabolites.

Indications:

FREEMAX™ is indicated for the relief of pain and inflammation in both acute and chronic conditions like;

◆ osteoarthritis ◆ rheumatoid arthritis ◆ ankylosing spondylitis ◆ dental pain
◆ gynaecological pain ◆ lower back pain

Dosage and administration:

The recommended dosages of ***FREEMAX***™ are:

- **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.
- **Elderly:** The pharmacokinetics of ***FREEMAX***™ is not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.
- **Renal insufficiency:** There is no evidence that the dosage of ***FREEMAX***™ needs to be modified in patients with mild renal impairment but like with all NSAIDs it should be assessed whether the benefits outweigh the risks.
- **Hepatic insufficiency:** There is some evidence that the dose of ***FREEMAX***™ should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100 mg be used.

Contraindication:

Aceclofenac is contraindicated in patients who have previously shown hypersensitivity reactions in response to other NSAIDs used before. Aceclofenac should not be administered to patients with moderate to severe renal impairment, active or suspected peptic ulcers or gastrointestinal bleeding.

Use in pregnancy and 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 outweigh the possible risks to the fetus.

Side effects:

Generally aceclofenac is well tolerated. The majority of adverse reactions reported have been reversible and of a minor nature; these include gastrointestinal disorders (dyspepsia, abdominal pain, nausea and diarrhea), occasional occurrence of dizziness. Dermatological complaints including pruritus, rash and abnormal (high or low) hepatic enzyme and serum creatinine levels have occasionally been reported.

Precaution:

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 prophyria or coagulation disorders. Patients suffering from severe hepatic impairment must be monitored.

Drug interactions:

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

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

Anticoagulants: Like other NSAIDs, Aceclofenac may enhance the activity of anticoagulants. Close monitoring of patients on combined anticoagulants and Aceclofenac therapy is requred.

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

Storage:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

Commercial Pack:

FREEMAX™ tablet : Each box contains 5 x 10 tablets in Alu-Alu blister strip.

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Manufactured by:
Nuvista Pharma Limited
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A subsidiary of Beximco Pharmaceuticals Ltd.

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