

Tolmic®

Tolfenamic Acid

Tablet

Description

Tolfenamic Acid is an NSAID with anti-inflammatory, analgesic and antipyretic effects. It is a prostaglandin synthesis inhibitor and a leukotriene synthesis inhibitor.

Indications

Acute migraine.

Dosage and Administration

For acute attacks : 200 mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory response is not obtained.

Use in Children : A pediatric dosage regimen has not yet been established.

Use in Elderly: Normal adult dose.

Use in Pregnancy and Lactation

In pregnancy: Reproduction studies in animals have not shown any signs of fetal damage. Controlled studies in pregnant women are not available. As is the case with the use of other NSAIDs, tolfenamic acid should not be given in the last trimester, due to risks of premature closure of the ductus arteriosus and prolonged parturition.

In lactation: Tolfenamic acid is excreted to such a very small extent in mothers' milk that it should be without risk to the breast-fed baby.

Side Effects

Tolfenamic Acid is well tolerated at the recommended dosage and seldom causes side effects which include diarrhea, nausea, epigastric pain, vomiting, urticaria, allergic skin reactions etc.

Contraindications

Active peptic ulceration. Significantly impaired kidney or liver function. Tolfenamic Acid is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.

Drug Interactions

Anticoagulants : In patients treated with anticoagulants, close monitoring of blood coagulation is recommended. **Diuretics :** The effect of loop diuretics may be reduced. **Lithium :** The effect of lithium may be increased.

Special Precautions for Use

As is the case with other NSAIDs, tolfenamic acid should be used with caution in patients with a history of gastrointestinal ulceration, or impaired liver or kidney function.

Preclinical Safety Data

The therapeutic index for tolfenamic acid is high, and gastrointestinal ulceration and kidney changes have only been seen with oral doses approximately 6-10 times the maximum therapeutic dose recommended for tolfenamic acid. In human volunteers, tolfenamic acid did not affect renal function.

Pharmaceutical Precautions

Store in a cool and dry place. Keep out of reach of children.F

Commercial Pack

Tolmic® tablet: Box containing 30 tablets in 3x10's blister strips. Each tablet contains Tolfenamic Acid BP 200 mg.

Manufactured by

Beximco Pharmaceuticals Ltd.

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