X-tol

Tolfenamic Acid BP

COMPOSITION:

X-tol 200 mg tablet: Each film-coated tablet contains Tolfenamic acid BP 200 mg.

PHARMACOLOGY:

Tolfenamic acid (N-2-methyl-3-chlorophenyl anthranilic acid) belongs to the fenamate group and is a potent inhibitor of cyclooxygenase enzyme, thus it inhibits the synthesis of important inflammatory mediators such as thromboxane (TX) B2 and prostaglandin (PG) E2. Prostaglandins are responsible for causing swelling, pain and inflammation associated with these conditions. It acts not only by inhibiting prostaglandin synthesis, but also has direct antagonistic action on its receptors.

PHARMACOKINETIC PROPERTIES:

Absorption: Readily absorbed from GI tract. *Peak plasma concentration:* 60-90 min. *Bioavailability:* 85%. *Protein binding:* 99%. *Plasma half-life:* 2 hours. *Metabolism:* Metabolised in the liver. Tolfenamic acid undergoes enterohepatic circulation. *Excretion:* Excreted in urine (90%) and faeces.

INDICATIONS:

Tolfenamic acid is used specifically for relieving the pain of migraine headache and also recommended for use as an analgesic in post-operative pain and fever.

DOSAGE & ADMINISTRATION:

Route of administration: X-tol tablet should be administered orally according to dosage guidelines.

Adult: Acute migraine attacks: 200 mg when first symptoms appear and may be repeated once after 1-2 hour(s). Mild to moderate pain: 100-200 mg tid.

Renal impairment: Dose adjustments may be needed. Severe renal impairment: Avoid.

Children: Paediatric dosage regimen has not yet been established.

Tolfenamic acid should be taken with food. Take water during or immediately after meals.

CONTRAINDICATIONS:

- Active peptic ulcer or bleeding in the gut
- Severe heart, kidney or liver failure

WARNINGS & PRECAUTIONS:

Precaution should be taken for patients with asthma, bronchospasm, bleeding disorders, cardiovascular diseases, peptic ulceration, hypertension, infection; liver, cardiac or renal function impairment and elderly. Increase water intake or dose reduction to reduce dysuria.

SIDE-EFFECTS:

The drug is generally well-tolerated.

Common Side-effects: Dysuria especially in males; diarrhoea, nausea, epigastric pain, vomiting, dyspepsia, erythema, headache, tremor, euphoria, fatigue, pulmonary infiltration & haematuria.

Rare Side-effects: Potentially fatal: Blood dyscrasias and hepatitis.

USE IN PREGNANCY & LACTATION:

Use in Pregnancy: This medicine is not recommended for use during pregnancy unless considered essential by physician. Not to be given during the third trimester of pregnancy.

Use During Lactation: NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

DRUG INTERACTIONS:

The rate of absorption of Tolfenamic acid increases with Metoclopramide and Magnesium hydroxide but decreases with Aluminium hydroxide. Risk of bleeding with anticoagulants and other NSAIDs increases when use with Tolfenamic acid. It decreases antihypertensive response to loop diuretics, β-blockers and ACE inhibitors. Co-administration increases plasma concentration of Lithium, Methotrexate and cardiac glycosides. It also increases the risk of nephrotoxicity with ACE inhibitors, Cyclosporin, Tacrolimus or diuretics.

OVERDOSE:

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, diarrhoea, excitation, coma, drowsiness, dizziness, tinnitus, fainting and convulsions. In case of significant poisoning, acute renal failure and liver damage are possible. Patients should be treated symptomatically as required.

STORAGE:

Store below 30ºC Temperature in a dry place. Keep away from light. Keep out of the reach of children.

PACKING:

X-tol 200 mg tablet: Each box contains 30 tablets in alu-alu blister strip.

Manufactured by:

Novatek Pharmaceuticals Ltd.

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