

# Tofix<sup>®</sup>

Tolfenamic Acid



## COMPOSITION:

Tofix<sup>®</sup> 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 it also has direct antagonistic action on its receptors.

## INDICATION:

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

## DOSE & ADMINISTRATION:

Adult:

- **Acute migraine attacks:** 200 mg when symptoms appear may be repeated once after 1-2 hour.
- **Mild to moderate pain:** 100-200 mg tid
- **Renal impairment:** Dose adjustments may be needed.
- **Severe renal impairment:** Avoid.

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

or as directed by the physician. Tolfenamic acid should be taken with or after food.

## CONTRA-INDICATION:

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 NSAIDs.

## WARNING AND PRECAUTION:

Precaution should be needed for patients with asthma bronchospasm, bleeding disorders, cardiovascular diseases, peptic ulceration, hypertension, liver infection, cardiac or renal function impairment and elderly.

## SIDE EFFECTS:

Tolfenamic Acid is well tolerated at the recommended dose. Side effects includes painful urination especially in males, diarrhea, nausea, stomach pain, vomiting, indigestion, redness of the skin, headache, tremor, emotional, fatigue and pulmonary infiltration.

## USE IN PREGNANCY & LACTATION:

Pregnancy: Pregnancy Category- C. Studies in pregnant women have not been established. So, 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.

Lactation: Tolfenamic Acid appears in breast milk in very low concentrations. So, it should be avoided when breastfeeding.

## USE IN CHILDREN & ADOLESCENTS:

The safety and efficacy of Tolfenamic Acid have not been established in children younger than 18 years.

## DRUG INTERACTION:

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, B-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, Ciclosporin, Tacrolimus or diuretics.

## OVERDOSE:

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

## STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

## PACKING:

Tofix<sup>®</sup> Tablet: Each box contains 3X10's tablets in Alu-Alu blister pack.



Manufactured by

**Team Pharmaceuticals Ltd.**

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