Migrex® 200

Tolfenamic acid 200 mg

Presentation
Migrex®200 mg tablet: Each tablet contains Tolfenamic acid BP 200 mg.

Description
Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) belongs to the fenamate group and is a potent inhibitor of cyclo-oxygenase 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.

Pharmacokinetic properties
Absorption: Readily absorbed from GI tract. Peak plasma concentration: 60-90 min. Bioavailability: 85%. Distribution: 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
Adult:
Acute migraine attacks: 200 mg when 1st symptoms appear may be repeated once after 1-2 hr.
Mild to moderate pain: 100-200 mg tid.

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

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

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

Precautions
Precaution should be needed 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.

Pregnancy & Lactation
Pregnancy: This medicine is not recommended for using during pregnancy unless considered essential by doctor. Not to be given during the third trimester of pregnancy.
Lactation: NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

Side effects
Dysuria especially in males; diarrhoea, nausea, epigastric pain, vomiting, dyspepsia, erythema, headache, tremor, euphoria, fatigue, pulmonary infiltration & haematuria. Potentially fatal: Blood dyscrasias and hepatitis.

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, Ciclosporin, Tacrolimus or diuretics.

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

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.

How to store
Store in a cool and dry place, away from light. Keep out of the reach of children.

Commerical Packaging
Migrex®200 mg tablet: Each box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhaka, Bangladesh
® Registered Trademark

V.N. 01
MGT