MINOPA

Tolfenamic Acid

COMPOSITION:
Minopa Tablet: Each 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 cyclo-oxygenase enzyme, thus 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 a 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 hr. Distributed into breast milk.
Metabolism: Metabolised in the liver. Tolfenamic acid undergoes enterohepatic circulation.
Excretion: Excreted in urine (90%) and faeces.

INDICATION:
Minopa is used specifically for relieving the pain of migraine headaches and also recommended for use as an analgesic in post-operative pain, and fever.

DOSAGE AND ADMINISTRATION:
Acute migraine attacks
Adult: 200 mg when 1st symptoms appear may be repeated once after 1-2 hr.
Renal impairment: Dose adjustments may be needed. *Severe:* Avoid.
Mild to moderate pain
Children: A paediatric dosage regimen has not yet been established. *Adult:* 100-200 mg tid.
Renal impairment: Dose adjustments may be needed. *Severe:* Avoid. It should be taken with food. Take water/ or immediately after meals.
Preclinical safety data
The therapeutic index for **Minopa** 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.
Special Precautions
Asthma, bronchospasm, bleeding disorders, cardiovascular diseases, history of peptic ulceration, hypertension, patients with infections, liver, cardiac, or renal function impairment. Increase water intake or dose reduction to reduce dysuria. CHF; elderly; lactation.

SIDE EFFECT:
Dysuria especially in males; diarrhoea, nausea, epigastric pain, vomiting, dyspepsia, erythema, headache. Tremor, euphoria, fatigue, pulmonary infiltration, & haematuria. Potentially Fatal: Blood dyscrasias, toxic hepatitis.

CONTRAINDICATION:
Not to be used in
• Children and adolescents under 18 years of age
• People with an active peptic ulcer or bleeding in the gut
• Severe heart failure, severe kidney failure, Severe liver failure

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• People taking other NSAIDs, including COX-2 inhibitors

This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor if you have previously experienced such an allergy. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately

PRECAUTION:

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.

USE IN PREGNANCY AND LACTATION:

Studies in pregnant women are not available. As is the case with the use of other NSAIDs, tolfeamic acid should not be given in the last trimester, due to risk of premature closure of the ductus arteriosus and prolonged parturition.

DRUG INTERACTION:

The rate of absorption of **Minopa** increases with metoclopramide and magnesium hydroxide and decreases with aluminium hydroxide. Risk of bleeding with anticoagulants and other NSAIDs increases when use with **Minopa**. It decreases antihypertensive response to loop diuretics, β-blockers and ACE inhibitors. Co-administration increases plasma concentrations of lithium, methotrexate and cardiac glycosides. It also increases the risk of nephrotoxicity with ACE inhibitors, ciclosporin, tacrolimus or diuretics.

OVERDOSAGE:

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.

PHARMACEUTICALS PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Minopa Tablet: Each box contains 3x10 tablets in Alu-Alu blister.

Manufactured By:

MEDICON

MEDICON Pharmaceuticals Ltd

Mirpur, Dhaka, Bangladesh