Only for the use of Medical Professionals

Namitol®

Tolfenamic acid

Description

Namitol® is a preparation of Tolfenamic acid which is an NSAID used to relieve the pain of migraine attack. It works by inhibiting the synthesis of prostaglandin and leukotriene.

Indication and usage

Namitol® is indicated for the treatment of acute migraine.

Dose and administration

To be taken preferably with or after food.

Adults:

1 Namitol® (200 mg) tablet when first symptoms appear may be repeated once after 1-2 hours if the response is not satisfactory.

Children:

A pediatric dosage regimen has not yet been established.

Elderly:

The lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Patients with renal impairment:

Dose adjustments may be needed. Severe: Avoid.

Use in pregnancy and lactation

Congenital abnormalities have been reported in association with NSAID administration in man, however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the fetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester of pregnancy is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the fetus.

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

Precautions

Caution should be taken in patients with asthma, bronchospasm, bleeding disorders, cardiovascular diseases, history of peptic ulcer disease, hypertension, patients with infections, liver, cardiac, or renal function impairment.

Side effects

Tolfenamic acid is a well tolerated drug at recommended dosage. However, side effects like dysuria especially in males; diarrhoea, nausea, epigastric pain, vomiting, dyspepsia, erythema, headache, tremor, euphoria, fatigue, pulmonary infiltration, etc may occur. Potentially fatal side effects like blood dyscrasias, toxic hepatitis may also take place.

Drug interactions

Increased rate of absorption of Tolfenamic acid with metoclopramide and magnesium hydroxide; decreased rate of absorption with aluminium hydroxide can occur. Increased risk of bleeding with anticoagulants and other NSAIDs; decreased antihypertensive response to loop diuretics, β-blockers and ACE inhibitors can also occur. Co-administration can increase the plasma concentrations of lithium, methotrexate and cardiac glycosides. There is an increased risk of nephrotoxicity with ACE inhibitors, cyclosporin, tacrolimus or diuretics.

Contraindications

Tolfenamic acid is contraindicated in patients with hypersensitivity to aspirin or other NSAIDs, active peptic ulcer disease, severe renal or hepatic impairment & during pregnancy (3rd trimester) and with a known hypersensitivity to Tolfenamic acid or any of the excipients.

Overdose

The symptoms of overdose include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible. Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amount. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Namitol® tablet : Each tablet contains Tolfenamic Acid BP 200 mg.

Packaging

Namitol® tablet : Carton of 30 tablets in blister pack

® Registered Trade Mark

ACI Limited