

Tufnil[®]

Tolfenamic acid tablet

DESCRIPTION

Tufnil[®] is a preparation of tolfenamic acid. It is an NSAID with anti-inflammatory, analgesic and antipyretic effects. Tolfenamic acid acts by inhibiting prostaglandin and leukotriene synthesis.

INDICATION

Acute migraine.

DOSAGE AND ADMINISTRATION

Adults: 200 mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory response is not obtained.

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

Elderly: Normal adult dose.

CONTRAINDICATION

Tolfenamic acid is contraindicated in active peptic ulceration, significantly impaired kidney or liver function and in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs.

SIDE-EFFECTS

Tolfenamic acid is well tolerated at the recommended dosage. The side effects include diarrhoea, nausea, epigastric pain, vomiting, dyspepsia, isolated reports of gastric ulceration, drug exanthema, erythema, pruritus, urticaria and occasional harmless dysuria in the form of smarting during urination in males. The occurrence is correlated with the concentration of a metabolite and is most probably due to local irritation of the urethra. Increased consumption of liquid or reduction of the dose diminishes the risk of smarting. The urine may, due to coloured metabolites, become a little more lemon-coloured. As is the case with the use of other NSAIDs, the occasional side effects include headache, vertigo, tremor, euphoria, fatigue, isolated cases of

dyspnoea, pulmonary infiltration, bronchospasm and asthma attack, isolated cases of thrombocytopenia, anemia and leucopenia, isolated cases of reversible liver function disturbances and toxic hepatitis.

PRECAUTIONS

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

Pregnancy: Reproduction studies in animals have not shown any signs of fetal damage. Controlled studies in pregnant women are not available. As is the case with 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 is excreted to such a very small extent in mothers' milk that it should be without risk to the breast-fed baby.

DRUG INTERACTIONS

In patients treated with anticoagulants, close monitoring of blood coagulation is recommended. The effect of loop diuretics may be reduced. The effect of lithium may be increased.

PHARMACEUTICAL PRECAUTION

Store in a cool and dry place, protect from light. Keep out of reach of children.

PACKAGING

Tufnil[®] tablet: Box containing 4 strips of 10 tablets each. Each tablet contains tolfenamic acid BP 200 mg.

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Manufactured by

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