Toti®

Ketotifen Tablet/Syrup

DESCRIPTION

Toti® is the preparation of ketotifen fumarate, which is an antihistamine with prolonged preventive effect on the frequency and intensity of the asthma attacks. It is associated with reduction of histamine, serotonin and other mast cell mediators release and simultaneous selective blocking of the H_1-receptors. As a result of the later effects, the level of the cell cAMP is enhanced and eosinophilic infiltration is inhibited. Although the preparation influences favorably expectoration, it does not cope the asthmatic attacks, but only prevents their appearance.

INDICATIONS

Toti® is indicated for long-term prevention of all forms of the bronchial asthma, allergic bronchitis and asthma manifestations in allergic rhinitis. Prevention and treatment of allergic diseases, including: acute and chronic urticaria, atopic dermatitis and allergic rhinitis.

DOSAGE AND ADMINISTRATION

Toti® should be taken orally with meal.

Adults: 1 mg, 2 times daily, in the morning and in the evening. In case of insufficient effect after 4-week treatment the dose could be increased up to 2 mg, 2 times daily.

Children (6 months - 3 years): 0.5 mg (2.5 mL syrup), 2 times daily.

Children (older than 3 years): 1 mg, 2 times daily (in the morning and in the evening).

The treatment with ketotifen should be discontinued gradually, with gradual reduction of the dose within 2-4 weeks, in order to avoid the risk of asthma symptoms. It is advisable to continue treatment for 2-3 months.

CONTRAINDICATIONS

Ketotifen is contraindicated in patients with known hypersensitivity to ketotifen.

USE IN PREGNANCY AND LACTATION

Ketotifen should not be used during the first trimester of the pregnancy. In nursing women ketotifen is used only after precise consideration of the mother and the fetus risk/benefit ratio.

PRECAUTIONS

In patients, sensitive to the sedative effect of the preparation, initial dose should be half of the usual, which could be gradually increased. In order to avoid suprarenal insufficiency, in patients, treated regularly with corticosteroids, Ketotifen should be started after gradual reduction of the corticosteroid dose, or elongation of the interdosage intervals. In case of intercurrent infections ketotifen should not be discontinued. At the beginning of the treatment ketotifen may cause patient reaction disorders, which requires enhanced attention in drivers and machinery operating persons.

SIDE-EFFECTS

During the first several days of the treatment with ketotifen following adverse effects may appear: somnolence, xerostomia, mild dizziness, and fatigue, which are usually reversible with the treatment. In some patients body weight enhancement is seen, due to appetite increasing. Hypersensitivity is very rare side effect, seen in immunocompromized patients.

DRUG INTERACTIONS

Concomitant treatment with oral antidiabetic preparations enhances the risk of reversible thrombocytopenia. ketotifen may potentiate the effect of the sedative hypnotic, and antihistamine medicines, as well as alcohol. The preparation could be combined with antiseptic and antibacterial medicines.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Toti® tablet : Box containing 10 strips of 10 tablets each. Each tablet contains ketotifen fumarate BP equivalent to ketotifen 1 mg.

Toti® syrup : Bottle containing 100 mL syrup. Each 5 mL syrup contains ketotifen fumarate BP equivalent to ketotifen 1 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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