

Prescription Only



Presentation

Zadit® syrup: Each 5 ml syrup contains Ketotifen Fumarate BP equivalent to 1 mg Ketotifen.

Description

Ketotifen 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 H₁-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

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

Dosage and Administration

Ketotifen should be taken orally with meal. *Adult:* 1 mg, 2 times daily, in the morning and in the evening. In case of insufficient effect after 4-week treatments, 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 recidivating. It is advisable the treatment to continue 2-3 months.

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 immuno compromised patients.

Contraindications

Ketotifen is contraindicated in patients with known hypersensitivity to Ketotifen.

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.

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 gradually reducing 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. *In pregnancy:* Ketotifen has been categorized as pregnancy category C. *In lactating mother:* Caution should be exercised when Ketotifen Fumarate is administered to a nursing mother.

Overdosage

Clinical results have shown no serious signs or symptoms after the ingestion of up to 20 mg of Ketotifen Fumarate.

Pharmaceutical Precautions

Store at below 30°C in a dry place protected from light. Keep out of reach of children.

Commercial Packs

Zadit® syrup: Bottle containing 100 ml syrup.

Manufactured by :



POPULAR PHARMACEUTICALS PLC.

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