Ketomar®

Ketotifen

Presentation

Ketomar® Tablet : Each tablet contains Ketotifen Fumarate BP equivalent to Ketotifen 1 mg.
Ketomar® Syrup : Each 5 ml syrup contains Ketotifen Fumarate BP equivalent to Ketotifen 1 mg.

Description

Ketotifen is a nonbronchodilator anti-asthmatic drug which inhibits the effects of certain endogenous substances known to be inflammatory mediators. In addition, Ketotifen is a potent anti-allergic substance possessing a powerful and sustained noncompetitive histamine (H_1) receptor blocking property.
Ketotifen is a type of asthma medication which, when taken every day and used along with other anti-asthmatic medications, may reduce the frequency, severity and duration of asthma symptoms or attacks in patients. It may also lead to a reduction in daily requirements of other anti-asthmatic medications such as Theophyllines and β_2-agonists, without the deterioration in pulmonary functions (FEV_1, FVC and PEFR). The prophylactic activity of Ketotifen may take several weeks to become fully established. Ketotifen will not abort established attacks of asthma.

Indications

- Prophylactic treatment of bronchial asthma
- Allergic rhinitis
- Allergic conditions such as hay fever, itchy rash or reactions to insect bites
- Allergic conjunctivitis

Dosage and Administration

(Ketotifen may be taken with or without food)

Age	Ketomer Tablet
Above 3 years and Adults	1 mg twice daily (once in the morning & once in the evening)
Elderly	Same as adult dose or as advised by the physician
	Ketomer Syrup
6 months to 3 years	0.25 ml / kg body weight, twice daily (once in the morning & once in the evening)

* **Missed dose-** If a dose of this medicine is missed that should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and the regular dosing schedule should be maintained. Dose should not be doubled in case of a missed dose.

Side-effects

Drowsiness, and in isolated cases dry mouth and slight dizziness may occur at the beginning of treatment but usually disappear spontaneously after a few days.

Precautions

Symptomatic and prophylactic anti-asthmatic drugs (Xanthine derivatives, β_2-agonists, Sodium Cromoglycate, Corticosteroids) already in use should not be reduced immediately when treatment with Ketotifen is initiated. This applies especially to Systemic Corticosteroids and ACTH injections because of the possible existence of adrenocortical insufficiency in steroid-dependent patients. During the first day of treatment with Ketotifen, reactions may be impaired and patients should be warned not to take charge of vehicle or machinery until the effect of Ketotifen treatment on the individual is known.

Use in Pregnancy and Lactation

Pregnancy: Its safety in human pregnancy has not been established. Ketotifen should therefore be given to pregnant women only in compelling circumstances.
Lactation: Ketotifen is excreted in breast milk. Therefore mothers receiving Ketotifen should not breast-feed.

Contraindications

Hypersensitivity to Ketotifen or any other components of the formulation.

Drug Interactions

A reversible fall in the thrombocyte count in patients receiving Ketotifen concomitantly with oral anti-diabetic agents has been observed in rare cases. So it has been suggested that this combination should therefore be avoided.
Ketotifen may potentiate the effects of sedatives, hypnotics, anti-histamines and alcohol.

Overdosage

The reported features of over dosage include confusion, drowsiness, disorientation, headache, bradycardia and respiratory depression. Elimination of the drug with gastric lavage or emesis is recommended. Otherwise general supportive treatment is all that is required shall be instituted.

Storage condition

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

Commercial Pack

Ketomar® Tablet: Each box contains 10 blister strips of 10 tablets.
Ketomar® Syrup: Each box contains an amber glass bottle containing 100 ml syrup and a measuring spoon.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhamrai Unit, Dhaka, Bangladesh

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