

Kefat Ketotifen Fumarate

COMPOSITION

Kefat Tablet: Each tablet contains Ketotifen Fumarate BP 1.38 mg equivalent to Ketotifen 1 mg.

Kefat Syrup: Each 5 ml syrup contains Ketotifen Fumarate BP 1.38 mg equivalent to Ketotifen 1 mg.

PHARMACOLOGY

Kefat (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 (H₁) 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 β₂-agonists, without the deterioration in pulmonary functions (FEV₁, FVC and PEF_R). The prophylactic activity of Ketotifen may take several weeks to become fully established. Ketotifen will not abort established attacks of asthma.

INDICATION

- 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

Kefat 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.

Kefat 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. Ketotifen may be taken with or without food.

CONTRAINDICATION

Hypersensitivity to Ketotifen or any other components of the formulation.

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, β₂-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.

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.

PHARMACEUTICAL PRECAUTION

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED

Kefat Tablet: Each box contains 10x10 tablets in blister pack.

Kefat Syrup: Each bottle contains 100 ml syrup with a measuring cup.

Manufactured by



MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh