

KETOF

KETOTFFEN FUMARATE INN

Compositions:

Ketof Tablet: Each tablet contains 1.38 mg Ketotffen Fumarate INN equivalent to 1.00 mg Ketotifen. Ketof Syrup: Each 5ml of Ketof syrup contains 1.38 mg Ketotifen Fumarate INN equivalent to 1.00 mg Ketotifen.

Pharmacology:

Ketof is a preparation of Ketotifen which has antihistaminic and anti-anaphylactic activity. It has been used similarly to sodium chromoglycate in the prophylactic treatment of asthma.

Dosage And Administration:

Adult: 1 mg (1 tablet or 1 teaspoonful) of Ketotifen twice daily with food. In severe cases the dose may be doubled. 0.5 to 1 mg at night may be preferable for the first few days of treatment if drowsiness is likely to be problem. Children (6 month to 3 years): 0.05 mg (0.25 ml Syrup) per kg body weight given twice daily. Use In elderly: Same as adult dose or as advised by the physician.

Contraindications:

A reversible fall in the platelet count has been observed in a few patients receiving ketotifen concomitantly with oral antidiabetic agents and it has been suggested that this combination should therefore be avoided. Although there is no evidence of any teratogenic effect, recommendations for Ketotifen in pregnancy or when breast feeding can not be given.

Warning And Precaution:

Treatment with existing anti-asthmatic treatment should be continued for at least 2 weeks after initiation of Ketotifen treatment due to the risk of exacerbation of asthma. For the same reason, Ketotifen should be discontinued gradually over a period of 2 to 4 weeks. Drowsiness may occur, particularly during the first days of treatment Patients should be warned not to drive or operate machinery until the effect of treatment on the individual is known, Ketotifen may also potentiate the effects of sedatives, hypnotics, antihistamines and alcohol For this reason patients should be advised to avoid alcoholic drinks.

Side Effects:

Sedation, drowsiness associated with occasional dry mouth, slight dizziness may occur at the beginning of treatment but usually disappears with continued use. CNS stimulation and weight gain also reported.

Use in Pregnancy and Lactation:

Although there is no evidence of any teratogenic effect, Ketotifen in pregnancy and lactation is not recommended.

Drug Interaction:

Ketotifen may potentiate the effects of sedatives, hypnotics, antihistamines and alcohols. A reversible fall in the platelet count has been observed in a few patients receiving Tifen concomitantly with oral antidiabetic agents and it has been suggested that this combination should therefore be avoided

Overdosage:

Overdose causes confusion, drowsiness, nystagmus, headache, disorientation. Bradycardia and respiratory depression should be watched for. Elimination of the drug with gastric lavage or emesis is recommended. Otherwise general supportive treatment can be instituted

Storage:

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

Packing:

Ketof Tablet: Box contains 10x10's tablets in blister strip. Ketof Syrup: Bottle contains 100 ml Ketotifen Fumarate syrup.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.