

**Description:**

Stafen (Ketotifen) is a potent antihistamine which exhibits strong histamine H₁ receptor-blocking activity. Also, it has been shown to possess antianaphylactic properties and is effective in preventing asthmatic attacks.

Composition:

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

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

Indications :

Stafen is indicated in the prophylactic treatment of bronchial asthma and also for the prevention and treatment of allergic conditions such as rhinitis, allergic bronchitis, acute and chronic urticaria, atopic dermatitis and conjunctivitis. The drug is particularly of value in patients who suffer from more than one atopic disease, e.g. asthma and rhinitis, when one formulation benefits both conditions.

Dosage & Administration:

The usual dose of **Stafen** is 1 mg twice daily with food increased if necessary to 2 mg twice daily; initial treatment in readily sedated patients, 0.5-1 mg at night. For children over 2 years, 1 mg twice daily with food. No dosage adjustment is required for the elderly patients.

Contraindications:

Concomitant therapy of Ketotifen and oral antidiabetics should be avoided.

Cautions:

Treatment with existing antiasthmatic drugs should be continued for at least 2 weeks after initiation of Ketotifen treatment owing 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 1st day of treatment, so patients taking Ketotifen should be warned not to drive or operate machinery until the effect of treatment on the individual is known.

Side-effects:

The symptomatic side effects of Ketotifen are few and relatively minor. The common side effects are drowsiness, dry mouth and slight dizziness. The incidence of drowsiness appears to decline during extended periods of treatment. Also, there have been occasional reports of CNS stimulation and weight gain. Fewer side effects are reported in children.

Use in Pregnancy & Lactation:

Although there is no evidence of teratogenic effects with the use of Ketotifen in pregnancy, use of Ketotifen should be avoided in pregnancy. Ketotifen is excreted in breast milk, therefore mothers receiving Ketotifen should not breast feed.

Drug Interactions:

A reversible fall in the platelet count has been observed in a few patients receiving Ketotifen concomitantly with oral antidiabetics and it has been suggested that this combination should therefore be avoided. Since Ketotifen has the properties of the antihistamines, it may potentiate the effects of other CNS depressant drugs such as alcohol, other antihistamines, hypnotics and sedatives.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Stafen Tablet: Each box contains 100's tablets in blister pack.

Stafen Syrup: Each bottle contains 100 ml syrup.



Manufactured by:

ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

20002538/03