# Aerofen®
Ketotifen

**Presentation**

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

**Therapeutic indications**

Prophylactic treatment of bronchial asthma. Symptomatic treatment of allergic conditions including allergic rhinitis, conjunctivitis, hay fever, urticaria, food allergy.

**Dosage and administration**

*Adults:* 1mg twice daily with food. If necessary the dose may be increased to 2mg twice daily.

*Children from 6 month to 3 years:* 1/2 teaspoon (2.5 ml) of the syrup,

*Children over 3 years:* 1 teaspoon (5ml) of the syrup or 1 tablet twice daily.

*Use in the elderly:* No evidence exists that elderly patients require different dosages or show different side effects from younger patients.

Patients' known to be easily sedated should be given 0.5-1mg at night for the first few days.

**Contraindications**

Hypersensitivity to ketotifen or any of the excipients. A reversible fall in the thrombocyte count in patients receiving ketotifen concomitantly with oral anti-diabetic agents has been observed in a few cases. This combination of drugs should therefore be avoided until this phenomenon has been satisfactorily explained.

**Special warnings and precautions for use**

Post-marketing surveillance has shown exacerbation of asthma in approximately 2 per 1000 patients. Since some of these asthmatic attacks might have been related to stopping existing treatment it is important to continue such treatment for a minimum of 2 weeks after starting ketotifen. This applies especially to systemic corticosteroids and ACTH because of the possible existence of adrenocortical insufficiency in steroid dependent patients: in such cases recovery of a normal pituitary-adrenal response to stress may take up to one year. If it is necessary to withdraw ketotifen, this should be done progressively over a period of 2 to 4 weeks. Symptoms of asthma may recur. If intercurrent infection occurs, ketotifen treatment must be supplemented by specific antimicrobial therapy.

**Interaction with other medicinal products and other forms of Interaction**

ketotifen may potentiate the effects of sedatives, hypnotics, antihistamines and alcohol. Patients should be warned not to take charge of vehicles or machinery until the effect of ketotifen treatment on the individual is known.

**Pregnancy and lactation**

Although there is no evidence of any teratogenic effect, recommendation for ketotifen in pregnancy cannot be given. Ketotifen is excreted in breast milk; therefore mothers receiving ketotifen should not breast feed.

**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. Occasionally symptoms of CNS stimulation have been observed. Weight gain has been reported.
Cystitis has been rarely described in association with ketotifen. Isolated cases of severe skin reactions (erythema multiforme, Stevens-Johnson syndrome) have been reported.

**Overdose**

The reported features of overdose include confusion, drowsiness, nystagmus, headache, disorientation, tachycardia, hypotension, reversible coma; especially in children, hyperexcitability or convulsions. Bradycardia and respiratory depression should be watched for. Elimination of the drug with gastric lavage or emesis is recommended. Otherwise, general supportive treatment is all that is required.

**Commercial Pack**

**Aerofen**® Tablet : Each box contains 5X10 Tablets in blister pack.
**Aerofen**® Syrup : Bottle containing 100 ml Syrup.

**Manufactured by :**
**Silva**
**Pharmaceuticals Limited**
Maijdee, Noakhali, Bangladesh