

## Ketotifen Fumarate BP

### Composition

**Tablet:** Each tablet contains Ketotifen Fumarate BP 1.38 mg equivalent to 1.00 mg Ketotifen.

**Syrup:** Each 5ml syrup contains Ketotifen Fumarate BP 1.38 mg equivalent to 1.00 mg Ketotifen.

### Pharmacology

**Ketifen®** (Ketotifen) is a potent antihistamine which exhibits strong H<sub>1</sub>-receptor blocking activity. In addition it has been shown to possess anti anaphylactic properties and is effective in preventing asthmatic attacks.

### Indications

1. Prophylaxis of bronchial asthma.
2. Allergic rhinitis (seasonal and perennial).
3. Allergic conjunctivitis.

### Dosage and Administration

**Route of administration:** Oral.

**Adult:** 1mg (1 tablet or 1 tsp syrup) twice daily with food. In severe cases the dose may be doubled.

**Children (Older than 3 years):** Same as adult dose.

**Children (6 months to 3 years): Asthma (Prophylaxis) :** 0.25 ml/kg of body weight, twice daily in the morning and evening.

**OR AS DIRECTED BY THE PHYSICIAN.**

### Contraindications

Hypersensitivity to Ketotifen or any other components of the formulation. Patients sensitive to Benzoate compounds should not take Ketotifen.

### Warning and Precautions

Symptomatic and prophylactic anti-asthmatic drugs already in use should not be reduced immediately when treatment with **Ketifen®** (Ketotifen) is initiated. This applies especially to systematic corticosteroids and ACTH injections.

### Side Effects

**Common side effect:** Drowsiness associated with occasional dry mouth and slight dizziness may occur at the beginning of treatment, but usually disappears after few days.

**Rare side effect:** Not any.

### Use in Pregnancy and Lactation

Adequate and well-controlled studies in humans have not been conducted. Women who take this medication should not breast feed.

### Use in Children and Adolescents

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

### Drug Interaction

**With medicine:** Ketotifen may potentiate the effects of sedative, hypnotics, antihistamines and alcohol.

**With food & others:** Food does not noticeably affect the absorption of Ketotifen.

### Overdose

Clinical results have shown no serious signs or symptoms after the overdosage of Ketotifen.

### Storage

Store below 30° C temperature & dry place, protected from light.  
Keep all medicines out of reach of children.

### Packing

**Tablet:** Each box contains 10x10 tablets in blisters.

**Syrup:** Each PET bottle contains 100 ml syrup with measuring spoon.

**\* Further information is available on request.**



Manufactured by:  
**The ACME Laboratories Ltd.**  
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For Health, Vigour and Happiness

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