

## 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**<sup>®</sup> (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.

