

Orotifen

Ketotifen

Composition

Orotifen Tablet: Each film coated tablet contains Ketotifen 1 mg (as Ketotifen Fumarate BP).

Orotifen Syrup: Each 5 ml syrup contains Ketotifen 1 mg (as Ketotifen Fumarate BP).

Pharmacodynamic properties

Ketotifen is a potent antiallergic drug which inhibits the effects of certain endogenous substances known to be inflammatory mediators. Ketotifen exerts a non-competitive blocking effect on histamine (H1) receptors.

Pharmacokinetic properties

After oral administration the absorption of Ketotifen is nearly complete. Bioavailability amounts to approximately 50% due to a first pass effect of about 50% in the liver. Maximal plasma concentrations are reached within 2-4 hours. Protein binding is 75%. Ketotifen has a short half-life of 3-5 hours. In urine about 1% of the substance is excreted unchanged within 48 hours and 60-70% as metabolites. The main metabolite in the urine is the practically inactive ketotifen-N-glucuronide.

Indications

- Prophylactic treatment of bronchial asthma.
- Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.

Dosage and Administration

Orotifen Tablet:

Adults : 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily in severe cases. **Children above 3 years :** 1 mg twice daily with food. **Use in elderly :** Same as adult dose or as advised by the physician.

Orotifen Syrup:

Adults : 1 mg (5 ml) twice daily with food. If necessary the dose may be increased to 2 mg (10 ml) twice daily in severe cases. **Children above 3 years :** 1 mg (5 ml) twice daily with food. **Use in elderly :** Same as adult dose or as advised by the physician.

Contraindication

Hypersensitivity to ketotifen or any of the excipients. A reversible fall in the platelet count has been observed in a few patients receiving Ketotifen concomitantly with oral antidiabetic agent and it has been suggested that this combination should therefore be avoided.

Precautions

Convulsions have been reported very rarely during Ketotifen therapy. It should be used with caution in patients with a history of epilepsy. Ketotifen may potentiate the effects of sedatives, hypnotic, antihistamines and alcohol.

Side Effects

A severe skin reaction can be caused due to allergic reaction. Feeling hyperactive, irritable or nervous, disturbed sleep, Cystitis, Weight gain, feeling sleepy are the possible 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.

Pregnancy and lactation

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

Storage conditions

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

Commercial Packs

Orotifen Tablet : Each box contains 10 blister packs of 10 tablets.

Orotifen Syrup : Each bottle contains 100 ml syrup.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Gazipur, Bangladesh



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