

Kofen[®]

Ketotifen

Description

Ketotifen fumarate (**Kofen[®]**) is a potent antihistamine that also inhibits release of inflammatory mediators. It is effective in preventing asthmatic attacks.

Mode of action

Ketotifen fumarate (**Kofen[®]**) exhibits strong H₁ receptor blocking activity. In addition it has been shown to possess antianaphylactic properties.

Pharmacokinetics

Ketotifen fumarate (**Kofen[®]**) is almost completely absorbed from the gastrointestinal tract following oral administration, but bioavailability is reported to be only about 50% due to hepatic first-pass metabolism. Peak plasma concentrations occur 2 to 4 hours after a dose by mouth. It is mainly excreted in the urine as inactive metabolites with a small amount of unchanged drug; the terminal elimination half-life is about 21 hours.

Composition

Kofen[®] Tablet: Each tablet contains Ketotifen Fumarate BP 1.38 mg equivalent to Ketotifen 1 mg.

Kofen[®] Syrup: Each 5 ml syrup contains Ketotifen Fumarate BP 1.38 mg equivalent to Ketotifen 1 mg.

Indications

The drug is of value in-patients who suffer from more than one atopic disease, e.g. asthma and rhinitis when one formulation benefits both conditions. It is effective in prophylaxis of bronchial asthma, allergic rhinitis and conjunctivitis.

Dosage & administration

Adult: 1-2 mg two times daily with food. Child: Over 2 years of age, 1 mg two times daily with food. Under 2 years, not recommended.

Contraindications

When drowsiness could be a hazard; Concomitantly with oral antidiabetic agents; Hypersensitivity to ketotifen or any of the excipients.

Side effects

The most common side effects are drowsiness and lethargy. Dry mouth and slight dizziness may also occur at the beginning of treatment.

Use in pregnancy & lactation

Ketotifen should be used in pregnancy and lactation, only if there is compelling reasons.

Precautions

Treatment with existing antiasthmatic agent should be continued for at least 2 weeks after initiation of ketotifen treatment owing to the risk of exacerbation of asthma.

Drug interactions

A reversible fall in the platelet count has been seen in a few patients receiving ketotifen 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, antihistamines, hypnotics, and sedatives.

Overdosage

Overdosage with upto 120 mg ketotifen have been reported. The main symptoms of acute overdosage include: drowsiness to severe sedation; confusion and disorientation; tachycardia and hypotension; convulsions, especially in children; hyperexcitability in children; reversible coma. Treatment should be symptomatic. If ingestion is very recent, emptying of the stomach may be considered. Administration of activated charcoal may be beneficial. If necessary, specific or symptomatic treatment and monitoring of the cardiovascular system and physostigmine for anticholinergic effects are recommended; if excitation or convulsions are present, short-acting barbiturates or benzodiazepines may be given.

Storage

Store in a cool and dry place, protected from light.

Packaging

Kofen[®] Tablet: Each carton contains 10X10 tablets in blister pack.

Kofen[®] Syrup: Each carton contains a bottle having 100 ml syrup.



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
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