ASTHAFEN TABLET

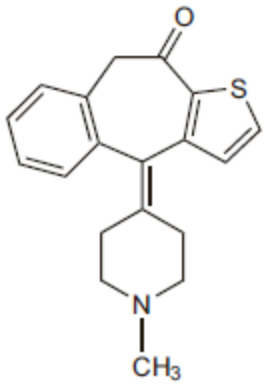
(Ketotifen Fumarate Tablets I.P.)

COMPOSITION

Each uncoated tablet contains:
Ketotifen fumarate I.P. equivalent to
Ketotifen base.....1 mg

DESCRIPTION

Ketotifen second-generation noncompetitive H1-antihistamine and mast cell stabilizer.



PHARMACOLOGY

Pharmacodynamic properties

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

Pharmacokinetic properties

After oral administration the absorption of ASTHAFEN TAB 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 is eliminated biphasically with a short half-life of 3-5 hours and a longer one of 21 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.

INDICATION

Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.

DOSAGE AND ADMINISTRATION

Adults

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

Children

(From 3 years of age): 1 mg twice daily with food. For patients for whom a tablet form may not be suitable, an alternative dosage form should be considered.

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 -1 mg 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 ASTHAFEN TAB 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.

WARNINGS AND PRECAUTIONS
ASTHAFEN Tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, of severe lactase deficiency or of glucose-galactose malabsorption should not take this medicine.

Convulsions have been reported very rarely during ASTHAFEN TAB therapy. As ASTHAFEN TAB may lower the seizure threshold it should be used with caution in patients with a history of epilepsy.

SPECIAL POPULATION
Pregnancy and lactation
Although there is no evidence of any teratogenic effect, recommendation for ASTHAFEN TAB in pregnancy cannot be given. Ketotifen is excreted in breast milk; therefore mothers receiving ASTHAFEN TAB should not breast feed.

Effects on ability to drive and use machines
During the first few days of treatment with ASTHAFEN TAB reactions may be impaired. Patients should be warned not to take charge of vehicles or machinery until the effect of ASTHAFEN TAB treatment on the individual is known.

DRUG INTERACTION
ASTHAFEN TAB 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 ASTHAFEN TAB treatment on the individual is known.

ADVERSE EFFECT
Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000) very rare (< 1/10,000), including isolated reports. Within each frequency grouping, adverse reactions are ranked in order of decreasing seriousness.

Infections and infestations	
Uncommon:	Cystitis
Immune system disorders	
Very rare:	Erythema multiforme, Stevens-Johnson syndrome, severe skin reaction
Metabolism and nutrition disorders	

Rare:	Weight increased
Psychiatric disorders	
Common:	Excitation, irritability, insomnia, nervousness
Nervous system disorders	
Uncommon:	Dizziness
Rare:	Sedation
Very rare	Convulsions
Gastrointestinal disorders	
Uncommon:	Dry mouth
Hepatobiliary disorders	
Very rare:	Hepatitis, increase in liver enzymes

Sedation, dry mouth and dizziness may occur at the beginning of treatment, but usually disappear spontaneously with continued medication. Symptoms of CNS stimulation, such as excitation, irritability, insomnia, and nervousness, have been observed particularly in children.

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.

Treatment should be symptomatic. Treatment with activated charcoal should be considered if the overdose has been taken within approximately one hour. If necessary, symptomatic treatment and monitoring of the cardiovascular system are recommended; if excitation is present, short acting barbiturates or benzodiazepines may be given.

Expiry date
Do not use later than the date of expiry.

Storage
Store protected from light and moisture at a temperature not exceeding 25°C

Presentation
ASTHAFEN is available as Blister strip of 10 tablets

MARKETED BY:

torrent

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