

ASTHAFEN

(Ketotifen Fumarate Tablets, 1mg & 1mg/5ml syrup)

Asthafen (ketotifen) possesses marked anti-anaphylactic properties. It is the first oral prophylactic therapy introduced for bronchial asthma. Asthafen is also indicated in symptomatic improvement of allergic conditions including rhinitis and conjunctivitis.

CLINICAL PHARMACOLOGY

The mechanism of its marked anti-anaphylactic properties is due to inhibition of release of local mediators from tissue mast cells and basophils, in particular SRS (slow reacting substance) and histamine, to the inhibition of SRS-induced bronchospasm in vivo and to calcium antagonistic properties. In addition, Asthafen exerts a sustained inhibitory effect on histamine reactions which, can be clearly dissociated from its anti-anaphylactic properties. Experimental investigations in asthmatic subjects have shown that Asthafen is as effective orally as a selective mast cell stabiliser administered by inhalation. Asthafen also reduces the number of asthmatic attacks, the severity of an attack and duration when given prophylactically in long term clinical trials. In some cases the patients were completely freed from attacks. Asthafen also reduces the dose of corticosteroids and bronchodilators in asthmatic patients. However, the prophylactic activity of Asthafen may take several weeks to become fully established. Asthafen will not abort established attacks of asthma.

INDICATIONS

Asthafen is indicated in prophylactic treatment of bronchial asthma, symptomatic improvement of allergic conditions including rhinitis and conjunctivitis.

CONTRAINDICATIONS

In few patients simultaneous administration of Asthafen with oral antidiabetic drugs is likely to cause a reversible fall in the thrombocyte count in patients.

PRECAUTIONS

In about 2 patients per 1000, Asthafen has been observed to exacerbate asthmatic attacks. This may be due to withdrawal of existing treatment and to avoid this it is important to continue such treatment for a minimum of 2 weeks after starting Asthafen therapy. This particularly applies to those patients who were taking systemic corticosteroids and ACTH. If intercurrent infection occurs Asthafen treatment must be supplemented by specific antimicrobial therapy.

During the first few days of treatment with Asthafen the normal reflexes may be impaired. Patients should be warned not to take charge of vehicles or machinery until the effect of ketotifen treatment is clearly manifested. Patients should be advised to avoid alcoholic drinks. Asthafen may potentiate the effects of sedative, hypnotics antihistamines and alcohol.

USE IN PREGNANCY AND LACTATION

Although there is no evidence of any teratogenic effect, Asthafen, in pregnancy or during lactation is not routinely recommended.

ADVERSE REACTIONS

Drowsiness, occasional complaint of dry mouth and slight dizziness may occur at the beginning of Asthafen treatment but usually disappear spontaneously after a few days.

DOSAGE AND ADMINISTRATION

For adults 1mg of Asthafen twice daily is recommended with food. If necessary the dose may be increased to 2mg twice daily. For children above 2 years the recommended dose is 1mg twice daily with food while in elderly patients the same doses as recommended for adult patients are administered. Patients, who are known to feel drowsy with other drugs, the treatment with Asthafen should be started with 0.5 to 1mg at night once a day for the first few days.

OVERDOSAGE

The signs and symptoms of overdosage with Asthafen include confusion, drowsiness, nystagmus, headache and disorientation. Bradycardia and respiratory depression should be watched for. Elimination of the drug with gastric lavage or emesis is recommended. Other general supportive treatment must be given.

PHARMACEUTICAL PRECAUTIONS

Protect tablets from heat and moisture.

PRESENTATION

Asthafen is available in blister strip of 10 tablets; each tablet containing 1.38mg ketotifen fumarate equivalent to 1mg ketotifen base. Asthafen syrup : In bottles containing 60ml. Syrup; each 5ml contains ketotifen fumarate equivalent to 1mg ketotifen base.



Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Baddi 173 205, Dist. Solan (H.P.) INDIA.

PRODUCT NAME	: Asthafen	COUNTRY : Reg. Eng.	LOCATION : Baddi	Supersedes A/W No.:			
ITEM / PACK	: Insert	NO. OF COLORS: 1	REMARK :				
DESIGN STYLE	: Front	PANTONE SHADE NOS.:	SUBSTRATE :				
CODE	: xxxxxxxxx-8883	Black	Activities	Department	Name	Signature	Date
DIMENSIONS (MM)	: 150 x 160		Prepared By	Pkg.Dev			
ART WORK SIZE	: S/S		Reviewed By	Pkg.Dev			
DATE	: 25-04-2014		Reviewed By	RA			
			Approved By	CQA			