AMITONE 1 mg/5 mL Syrup

ANTIHISTAMINE

Each 5 mL contains:
Ketotifen fumarate eq. to Ketotifen 1 mg

PRODUCT DESCRIPTION:
Clear, colorless syrup with raspberry flavor

MECHANISM OF ACTION:
Pharmacology
Ketotifen is a potent anti-allergic drug which inhibits the effects of certain endogenous substances known to be inflammatory mediators. Ketotifen exerts a non-competitive blocking effect on histamine (H_1) receptors.
Pharmacokinetics
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 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:
Oral
Use in adults
5 mL (1 teaspoonful) twice daily with food. If necessary the dose may be increased to 10 mL (2 teaspoonfuls) twice daily.
Use in children (from 3 years of age)
5 mL (1 teaspoonful) twice daily with food.
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 2.5 – 5 mL (1/2 – 1 teaspoonful) at night for the first few days.

PRECAUTION:
Convulsions have been reported very rarely during Ketotifen therapy. As Ketotifen may lower the seizure threshold it should be used with caution in patients with a history of epilepsy.
Pregnancy and Lactation
Although there is no evidence for any teratogenic effect, recommendation for Ketotifen in pregnancy cannot be given. Ketotifen is excreted in breast milk; therefore, mothers receiving Ketotifen should not breast feed.
****Warning: This preparation contains Sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.***

SIDE 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, < 1/1000); 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.

CONTRAINDICATION:
Hypersensitivity to Ketotifen or any of the excipients. A reversible fall in the thrombocyte count in patients receiving Ketotifen 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.

DRUG INTERACTION:
Ketotifen 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 Ketotifen treatment on the individual is known.

OVERDOSE AND TREATMENT:
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.

SHELF LIFE:
Two (2) years

STORAGE:
Store at temperature of not more than 30°C.

SUPPLY:
Bottle 100 mL

2/10/12

Manufactured by:
UNISON LABORATORIES CO., LTD.
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao,
Chachoengsao 24000 Thailand

Marketing Authorization Holder/ Importer:
MEDISPEC (M) SDN. BHD.
No. 55 & 57, Lorong Sempadan 2, (Off Boundary Road)
11400 Ayer Itam, Penang, Malaysia

C-ML/120912-07(MJ)
(www.emc.medicines.org.uk; *Drug Registration Guidelines Documents-Malaysia)

IAML 0040

13.5 cm
28 cm

PM Specification	Product Name	Code No.	Packaging Type	Thickness
	AMITONE 1 MG/5 ML	IIAML 0040	กระดาษไขเคลือบ	60 แกรม หนา = 0.08 mm.

1/10/12