



บริษัท ยูนิชั่น จำกัด
UNISON LABORATORIES CO., LTD.



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PART-I

Section E.8

Proposed Patient Information Leaflet



Unison Laboratories Co., Ltd.

PACKAGING MATERIALS

Revision	00
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AMITONE 1 mg/ 5 mL Syrup

Each teaspoonful (5 mL) of syrup contains:
Ketotifen fumarate eq. to Ketotifen 1 mg

AMITONE 1 mg/ 5 mL

ANTIHISTAMINE

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

- What is AMITONE 1 mg/ 5 mL Syrup?**
AMITONE 1 mg/ 5 mL Syrup contains the active ingredient Ketotifen fumarate, which 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.
- How much strength of AMITONE 1 mg/ 5 mL Syrup is available?**
AMITONE 1 mg/ 5 mL Syrup is available at the strength of 1 mg.
AMITONE 1 mg/ 5 mL Syrup is clear, colorless syrup with raspberry flavor. It is supplied as bottle of 100 mL.
- What is AMITONE 1 mg/ 5 mL Syrup for?**
Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.
- When should you not take AMITONE 1 mg/ 5 mL Syrup?**
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.
- How much and how often should you use AMITONE 1 mg/ 5 mL Syrup?**
Use in adults
1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily.
Use in children (from 3 years of age)
1 mg 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 0.5 1 mg at night for the first few days (for a 0.5 mg dose, an alternative dosage form to capsules should be given).

- What are the possible side effects of AMITONE 1 mg/ 5 mL Syrup?**
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.

- What other medicine or food should be avoided while taking AMITONE 1 mg/ 5 mL Syrup?**
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.
- What should you do if you miss a dose of AMITONE 1 mg/ 5 mL Syrup?**
Taking as soon as possible; not taking if almost time for next dose; not doubling doses.
- How should you keep AMITONE 1 mg/ 5 mL Syrup?**
Store at temperature of not more than 30°C, in a well-closed container.
- What are the signs and symptoms of AMITONE 1 mg/ 5 mL Syrup?**
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.
- What to do when you have taken more than the recommended dosage AMITONE 1 mg/ 5 mL Syrup?**
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.
- What care that should be taken when taking AMITONE 1 mg/ 5 mL Syrup?**
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 of 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.
- When should you consult your doctor?**
see Care That Should Be Taken Section.

- AMITONE 1 mg/ 5 mL Syrup is manufactured by:



UNISON LABORATORIES COMPANY, LIMITED
30 Ladkrabung Rd., Ladkrabung, 10520 Bangkok THAILAND

- AMITONE 1 mg/ 5 mL Syrup is imported and distributed by:

MEDISPEC (M) SDN BHD
No. 55 & 57, Lorong Sempadan 2, (Off Boundary Road)
11400 Ayer Itam, Penang, MALAYSIA