ASUMALIFE® TABLET 1MG

Ketotifen exerts potent antianaphylactic and antihistaminic effects. Its powerful and sustained H_1-receptor blocking activity can be clearly dissociated from its antianaphylactic properties. Ketotifen has been used in the prophylactic treatment of asthma.

Ingredient(s):
Each tablet contains :
Ketotifen Fumarate 1.38mg
(eq. to Ketotifen 1mg)

Pharmacodynamics:
1. Ketotifen is a potent antihistamine which exhibits strong H_1-receptors blocking activity. In addition it has been shown to possesses antianaphylactic properties and is effective in preventing asthmatic attacks.
2. Laboratory experiments suggest that the activity of the drug may be mainly due to the inhibition of release of chemical mediators from tissue mast cells and basophils, in particular histamine and the leukotriene, and to calcium antagonistic properties.
3. Ketotifen is extremely effective in protecting patients against histamine-induced bronchospasm both in single and when administered long term.

Pharmacokinetics:
Gastrointestinal absorption of Ketotifen following oral administration is rapid, with an absorption half-life of less than one hour. Peak plasma concentrations are achieved at 2 hours after dosing. 30 ~ 50 % of the drug is excreted in the urine and the remainder in the feces. The elimination half-life is 22 hours.

Indication(s):
Prophylactic treatment of bronchial asthma and symptomatic treatment of allergic rhinitis, dermatitis, urticaria and pruritus.

Route of Administration:
To be taken orally.

Dosage and Administration:
Adults and Children over 2 years of age : 1mg twice daily with morning and evening meals.
Children under 2 years of age : No clear evidence of efficacy and safety has been established.
To minimize the initial sedation with ketotifen, a progressive regimen is recommended during the first week of treatment commencing with one half the daily recommended dosage given in 2 divided doses or in a single dose given in the evening, followed within 5 days, by an increase to the full therapeutic dose.
Concomitant therapy : A progressive reduction in dosage of other asthma drugs, where clinically indicated, should be attempted only after 6 to 12 weeks of ketotifen therapy.
To be dispensed on physician's prescription.

Contraindications:
Contraindicated in patients with known hypersensitivity to ketotifen.

Precaution(s) / Warning(s):
1. The dose should be reduced gradually over a period of one week upon withdrawal to prevent the recurrence of the symptoms of asthma.

2. Care should be exercised when driving a vehicle or operating machinery because ketotifen may cause sedation.
3. Although there is no evidence of teratogenic effects, ketotifen fumarate should be given to pregnant women only if the potential benefit justifies the potential risk to the fetus.
4. It is not known whether Ketotifen Fumarate is excreted in breast milk. Asumalife should therefore be given to nursing mothers only if absolutely essential.

Drug Interactions:
1. Ketotifen may potentiate the effects of sedatives, hypnotic, antihistamines and alcohol.
2. Concomitant use of ketotifen with oral antidiabetic agent should be avoided as a reversible fall in the platelet count has been observed.

Side Effect(s) / Adverse Reaction(s):
There is a relatively low incidence of adverse reactions reported. Sedation, dry mouth, dizziness, increased appetite and weight gain may occur occasionally.
CNS stimulation including excitability and agitation in children has been reported.

Symptoms and Treatment for Overdosage, and Anti-Dote:
Overdosages with up to 120 mg ketotifen have been reported. The main symptoms of acute overdosage include: drowsiness to severe sedation; confusion and disorientation; tachycardia and hypotension; convulsion, especially in children; hyperexcitability in children; reversible coma. Treatment should be symptomatic. If ingestion is recent, the stomach should be emptied. If necessary, specific or symptomatic treatment should be instituted.

Shelf-Life:
2 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30ºC. Protect from light and moisture.

Product Description and Packing(s):
A white tablet, one side with a score and the other side impressed with the mark “YS”.
Blister packing of 10’s x 6, 10’s x 10, 10’s x 50, 10’s x 60 and 10’s x 100.
Plastic bottle of 60’s.
Plastic bottle of 500’s and 1000’s (for export only).

Y. S. P.®
Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
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