

U-KEFEN TABLETS 1 MG

U-KEFEN SYRUP 1MG/5ML

NAME AND STRENGTH OF ACTIVE INGREDIENT:

- (i) U-KEFEN TABLETS 1MG
Each tablet contains Ketotifen Fumarate equivalent to Ketotifen.....1mg
- (ii) U-KEFEN SYRUP 1MG/5ML
Each 5ml syrup contains Ketotifen Fumarate equivalent to Ketotifen.....1mg

PRODUCT DESCRIPTION:

- (i) U-KEFEN TABLETS 1MG
A white, scored, flat of diameter 7mm round tablet with 'MPI' marking.
- (ii) U-KEFEN SYRUP 1MG/5ML
A clear liquid with tutti frutti flavour and sweet taste.

PHARMACODYNAMICS:

Ketotifen has the properties of the antihistamines in addition to action on mast cells analogous to those of sodium cromoglycate. In addition to its antihistaminic action, inhibition of phosphodiesterases, blockade of calcium channels, inhibition of the release of mixture of leukotrienes known as slow-reacting substance of anaphylaxis (SRS-A) and functional antagonism of the effects of SRS-A have been demonstrated, and there is now some evidence for an effect on β 2-receptor or mediated reactions.

PHARMACOKINETICS:

Ketotifen fumarate is absorbed from the gastrointestinal tract and together with metabolites, is excreted in the urine and faeces. It has a very slow onset of action, it must be administered on a regular basis for 6-12 weeks before any beneficial effect is seen.

INDICATION:

Ketotifen is used in the prophylactic treatment of asthma and has also been given in the treatment of allergic conditions such as rhinitis and conjunctivitis.

RECOMMENDED DOSAGE:

Adults: 1mg of ketotifen (1 tablet or 5ml syrup) twice daily with food, increased if necessary to 2mg (2 tablets or 10ml syrup) twice daily.

Children over 2 years may be given 1mg (1 tablet or 5ml syrup) twice daily.

It must be administered on a regular basis for 6–12 weeks before any beneficial effects is seen. Patients known to be easily sedated should begin treatment with 0.5–1mg ($\frac{1}{2}$ to 1 tablet or 2.5 to 5ml syrup) at night for the first few days.

ROUTE OF ADMINISTRATION:

Oral

CONTRAINDICATIONS:

1. A reversible fall in the platelet count has been observed in a few patients receiving ketotifen concomitantly with oral anti-diabetic agents and it has been suggested that this combination should be avoided.
2. Ketotifen should not be given to patients with known hypersensitivity to the drug.
3. Ketotifen should not be given to nursing mother.

WARNINGS AND PRECAUTIONS:

1. Ketotifen has no role in the treatment of acute asthmatic attacks or status asthmaticus. Withdrawal of ketotifen may lead to recurrence of the symptoms of asthma. Should withdrawal be necessary it has been suggested that the dose be reduced gradually over a period of one week.
2. This drug may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic beverages.
3. It should be given to pregnant women only under compelling circumstances. Do not use if breastfeeding.

INTERACTIONS WITH OTHER MEDICAMENTS:

Ketotifen may potentiate the effects of sedatives, hypnotics, antihistamines and alcohol.

PREGNANCY AND LACTATION:**Pregnancy**

Safety of its use during pregnancy has not been established. The administration of ketotifen during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. Women who are pregnant should consult a doctor before use.

Lactation

Ketotifen may be secreted into breast milk. Do not use if breastfeeding.

SIDE EFFECTS:

Sedation, tiredness, weight gain and dry mouth are the most common side-effects. Dizziness, nausea, headache, exacerbation of asthma, bronchospasm, and status asthmaticus occurred in some patients.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms : Symptoms of overdosage include drowsiness, confusion, dyspnoea, bradycardia or tachycardia, disorientation and convulsion. Nystagmus, headache, hypotension and reversible coma especially in children. Bradycardia and respiratory depression should be watched.

Treatment : Withdrawal of the drug is usually all that is necessary. Treatment should be symptomatic. The stomach should be emptied if the drug has been ingested recently. If necessary, symptomatic treatment and monitoring of the cardiovascular system, excitation and convulsion (may be treated using short-acting barbiturates/benzodiazepines).

EFFECT ON ABILITY TO DRIVE AND USE MACHINE

Ketotifen may cause dizziness, sedation and tiredness. Affected patients should not drive or operate machinery.

DOSAGE FORMS AND PACKAGING AVAILABLE:

- (i) U-KEFEN TABLETS 1MG
 - Dosage Form: Tablet
 - Packing size: Blister Pack: 50 x 10's

- (ii) U-KEFEN SYRUP 1MG/5ML
 - Dosage Form: Liquid
 - Packing size: 100ml in amber plastic bottle

NAME AND ADDRESS OF MANUFACTURER/PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Pulau Pinang, Malaysia.

DATE OF REVISION:

07/09/2018