

Ridair[®]

Ketotifen

COMPOSITION:

Ridair[®] 1 Tablet: Each tablet contains Ketotifen Fumarate BP 1.38 mg equivalent to 1 mg Ketotifen.

Ridair[®] Syrup: Each 5 ml syrup contains Ketotifen Fumarate BP 1.38 mg equivalent to 1 mg Ketotifen.

PHARMACOLOGY:

Ridair[®] is a preparation of Ketotifen, which has anti-allergic properties and has been used similarly, to sodium chromoglycate in the prophylactic treatment of asthma. It also has the properties of an antihistamine. Ridair[®] (Ketotifen) possesses marked anti-anaphylactic properties and is effective in preventing asthmatic attack. Ridair[®] (Ketotifen) 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 Ketotifen is as effective orally as a selective mast cell stabilizer administered by inhalation. Antihistamines were ineffective in those tests. The effectiveness of Ketotifen has been studied in long term clinical trials. Asthma attacks were reduced in number, severity and duration and in some cases, the patients were completely freed from attacks. Progressive reduction of corticosteroids and/or bronchodilators was also possible. The prophylactic activity of Ketotifen may take several weeks to become fully established. Ketotifen will not abort established attacks of asthma.

INDICATION:

- * Prophylactic treatment of bronchial asthma.
- * Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.

DOSE & ADMINISTRATION:

Adults: 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily in severe cases. Children above 3 years: 1 mg twice daily with food. Patients known to be easily sedated should begin treatment with 0.5 to 1 mg at night for the first few days or as directed by the physician. Use in elderly: Same as adult dose or as advised by the physician.

CONTRA-INDICATION:

A reversible fall in the platelet count has been observed in a few patients receiving Ketotifen concomitantly with oral antidiabetic agent and it has been suggested that this combination should therefore be avoided. Although there is no evidence of any teratogenic effect, recommendations for Ketotifen in pregnancy or when breast feeding can not be given.

WARNING AND PRECAUTION:

It is important to continue the previous treatment for a minimum of two weeks after starting Ketotifen to avoid the possibility of exacerbation of asthma. This applies specially to systemic corticosteroids and ACTH because of the possible existence of adrenocortical insufficiency in steroid dependent patient. If inter current infection occurs, Ketotifen treatment must be supplemented by specific antimicrobial therapy. During the first day of treatment with Ketotifen, reactions may be impaired and patients should be warned not to take charge of vehicle or machinery until the effect of Ketotifen treatment on the individual is known. Patients should be advised to avoid alcoholic drinks.

SIDE EFFECTS:

Drowsiness and in isolated cases, dry mouth and slight dizziness may occur at the beginning of treatment but usually disappear spontaneously after a few days.

USE IN PREGNANCY & LACTATION:

Pregnancy: Its safety in human pregnancy has not been established. Ketotifen should therefore be given to pregnant women only in compelling circumstances.

Lactation: Ketotifen is excreted in breast milk. Therefore mothers receiving Ketotifen should not breast-feed.

USE IN CHILDREN & ADOLESCENTS:

Ketotifen syrup is not recommended below 6 month age of child.

DRUG INTERACTION:

A reversible fall in the thrombocyte count in patients receiving Ketotifen concomitantly with oral anti-diabetic agents has been observed in rare cases. So it has been suggested that this combination should therefore be avoided. Ketotifen may potentiate the effects of sedatives, hypnotics, anti-histamines and alcohol.

OVERDOSE:

The reported features of overdosage include confusion, drowsiness, headache, bradycardia, respiratory depression etc. should be watched for. Elimination of the drug with gastric lavage or emesis is recommended. Otherwise general supportive treatment is all that is required shall be instituted.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Ridair[®] 1 Tablet: Each box containing 10x10's tablets in blister pack.

Ridair[®] Syrup: Each bottle contains 100 ml syrup and a measuring cup.



Manufactured by

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