130 mm X 150 mm

Only for the use of Medical Professionals

Prosma®

Ketotifen

Composition

Prosma® Tablet: Each tablet contains Ketotifen 1 mg as Fumarate BP.
Prosma® Syrup: Each 5 ml contains Ketotifen 1 mg as Fumarate BP.

Pharmacology

Prosma® is a non-bronchodilator anti-asthmatic drug with marked anti-anaphylactic and special antihistaminic properties. In addition, **Prosma®** exerts a powerful and sustained H_1-receptor blocking activity which can be clearly dissociated from its anti-anaphylactic properties.

Indication

Prosma® is indicated in long-term prevention of
- Bronchial asthma (all forms including mixed)
- Allergic bronchitis
- Asthmatic symptoms associated with hay fever

Prosma® is also indicated in prevention and treatment of
- Multi-system allergies
- Allergic rhinitis
- Skin and food allergy

Dose and administration

Route of administration: **Prosma®** should be taken in oral route.

Adults: The recommended dose of **Prosma®** is 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily in severe cases. Initial treatment in readily sedated patients is 0.5 mg (½ tablet) twice daily or 1 mg at night.

Children:
Children aged 3 years and above: **Prosma®** may be given 1 mg twice daily with meal.
Children aged 6 months to below 3 years: **Prosma®** 0.05 mg (0.25 ml of syrup) per kg of body weight twice daily, (in the morning and evening).

Contraindication

Ketotifen is contraindicated in patient with known hypersensitivity to ketotifen or any components of this product.

Warning and precaution

Previous anti-asthmatic treatment should be continued for a minimum of 2 weeks after initiation of ketotifen treatment. Exacerbation of asthma may occur related to stopping existing treatment. This applies especially to systemic corticosteroid and ACTH because of the possible existence of adrenocortical insufficiency in steroid dependent patients. In such cases recovery of a normal pituitary adrenal response to stress may take up to one year. If intercurrent infection occurs the treatment must supplemented with specific antimicrobial therapy.

Side effects

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

Use in pregnancy and 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 breastfeed.

Drug interaction

Drug interaction with medication: A reversible fall in the platelet count has been observed in few patients receiving ketotifen concomitantly with oral anti-diabetic agents and it has been suggested that this combination should therefore be avoided.

Drug interaction with food and others: Not applicable.

Overdose

Symptoms of overdose of ketotifen are drowsiness, confusion, dyspnoea, bradycardia or tachycardia, disorientation, convulsions, severe hypotension and reversible coma. If overdose occurs, treatment should be symptomatic and supportive.

Storage

Store in a cool (below 30ºC) and dry place protected from light. Keep away from the reach of children.

Packing

Prosma® Tablet: Carton of 100 tablets in blister.
Prosma® Syrup: Bottle of 100 ml.

® Registered Trade Mark

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030238/B

Prosma®

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