

Only for the use of medical professionals

Prosma[®]

Ketotifen Fumarate

Presentation:

Prosma[®] Tablet: Each tablet contains Ketotifen 1 mg as Fumarate BP.

Prosma[®] syrup: Each 5ml contains Ketotifen 1 mg as Fumarate BP.

Uses

Prosma[®] is a non-bronchodilator anti-asthmatic drug with marked anti-anaphylactic and special antihistamine properties. In addition, **Prosma[®]** exerts a powerful and sustained H₁ receptor blocking activity which can be clearly dissociated from its anti-anaphylactic properties.

It is indicated in long-term prevention of

- Bronchial asthma (all forms including mixed)
- Allergic bronchitis
- Asthmatic symptoms associated with hay fever

Prevention and treatment of

- Multi-system allergies
- Allergic rhinitis
- Skin and food allergy.

Dosage and administration

Adults: 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 0.5mg (1/2 tablet) twice daily or 1 mg at night.

Children over 3 years of age may be given 1 mg twice daily with meal. Children aged 6 months to 3 years 0.05 mg (0.25 ml syrup) per kg of body weight twice daily (in the morning and evening).

Contra-indications, warnings, etc.

Contra-indications: A reversible fall in the platelet count has been observed in few patients receiving Ketotifen concomitantly with oral antidiabetic agents and it has been suggested that this combination should therefore be avoided.

Use in pregnancy and lactation: It should not be used in pregnancy and during breast feeding, although there is no evidence of teratogenic effect.

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 upto one year. If intercurrent infections 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.

Pharmaceutical precautions

Store in a cool place (Below 30°C), protected from light & moisture.

Package quantities

Prosma® Tablet: Cartons of 100's tablet in strip.

Prosma® Syrup: Bottles of 100 ml.

® Registered Trade Mark



ACI Limited

Narayanganj, Bangladesh