Proasma
(Ketotifen)

پروزما
(کیٹوٹائفن)

An asthma prophylactic and anti-allergic agent.

Composition
Each tablet contains:
Ketotifen fumarate (B.P.).....1.38 mg
equivalent to ketotifen.....1 mg
Each 5 ml contains:
Ketotifen fumarate (B.P.).....1.38 mg
equivalent to Ketotifen..... 1 mg
Product Complies Platinum Specs.

Properties: Proasma is a non-bronchodilator anti-asthmatic drug with marked anti-anaphylactic properties and a specific antihistaminic effect.

Laboratory experiments, both in vitro and in vivo, have revelaed the following properties of Proasma, which may contribute to its anti-asthmatic activity.

- Inhibition, both of the acute bronchoconstrictor response, to PAF (Platelet Activating Factor) and of PAF-induced airway hyperresponsiveness.
- Inhibition of PAF-induced accumulation of eosinophils in the airways.
- Inhibition of the release of such chemical mediators as histamine and leukotrienes.
- Antagonism of acute bronchoconstriction due to leukotrienes.
- Reversal and prevention of experimentally-induced tachyphylaxis to isoprenaline.

In addition, **Proasma** exerts powerful and sustained H_1-receptor blocking activity which can be clearly dissociated from its anti-anaphylactic properties.

Pharmacokinetics: After oral administration the absorption of Proasma is nearly complete. Bioavailability amounts to approx. 50% due to a first pass effect of about 50% in the liver. Maximal plasma concentrations are reached within 2-4 hours. Protein binding is 75%. Ketotifen is eliminated biphasically with a short half-life of 3-5 hours and a longer one of 21 hours. In urine about 1% of the asubstance is exerted unchanged within 48 hours and 60-70% as metabolites. The main metabolites in the urine is pratically inactive ketotifen-N-glucuronide.

The pattern of metabolism in children is the same as in adults, but the clearance is higher in children.

Therefore, children above the age of 3 years require the same daily dosage

خوراک:
بالغ افراد:

ایک گولی پروزما (املی گرام) دن میں دومرتبہ (ترجیحاً کھانے کے ساتھ)۔ شروع شروع میں پروزما کے استعمال سے چند افراد میں تھوڑی بہت غنودگی (اونگھ) کی شکایت ہوسکتی ہے۔ لیکن دوا کے مسلسل استعمال سے جلد ہی یہ شکایت دور ہو جاتی ہے۔ غنودگی کی صورت میں آدھی گولی دن میں دومرتبہ سے شروع کریں اور خوراک کو بتدریج بڑھاتے جائیں۔

بچوں کی خوراک:
چھ ماہ تا تین سال: ۵ء۰ ملی گرام (آدھی گولی یا آدھا چمچ شربت) دن میں دومرتبہ۔

تین سال اور اس سے زیادہ: ایک گولی پروزما (املی گرام) یا ایک چمچ شربت دن میں دومرتبہ۔

احتیاط:
پہلے سے زیرِ استعمال دوا کو ایک دم ترک نہیں کرنا چاہئے۔ پروزما کے استعمال سے شروع کے کچھ ایام میں مستعدی متاثر ہوسکتی ہے۔ اس لئے گاڑی یا مشین چلانے میں خلل واقع ہوسکتا ہے۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔

دوا بچوں کی پہنچ سے دور رکھیں۔

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:
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QAR No. 050259-1126

regimen as adults. From the kinetic date, it is recommended that in children aged from 6 months to 3 years, half of the adult dose be administered.

Indications:

- Long-term prevention of
  - bronchial asthma (all forms, incl. mixed)
  - allergic bronchitis
  - asthmatic symptoms associated with hay fever.

- Prevention and treatment of
  - multi-system allergies
  - Allergic rhinitis
  - Allergic skin reactions

In the prevention of bronchial asthma it may take several weeks of treatment to achieve the full therapeutic effect. Proasma is not effective in aborting established attacks of asthma.

Dosage :

Adults: One **Proasma** tablet (1 mg) twice daily (with morning and evening meals). In patients susceptible to sedation, a progressive regimen is recommended during the first week of treatment commencing with ½ tablet twice daily, increasing to the full therapeutic dose, if necessary the dosage may be increased up to 4 mg a day in two divided doses.

Children: Children aged 6 months to 3 years :
0.5 mg (1/2 scored table, or 2.5 ml syrup)
twice daily. Children age 3 years and above :
1 Proasma tablet (1 mg) twice daily.
Clinical observations reflect pharmacokinetic findings and indicate that children may require a higher dose in mg/kg body weight than adults in order to obtain optimal results. This higher dosage is as well tolerated as lower doses (see also under “Pharmacokinetics”).

Contraindications:
Hypersensitivity to the drug.

Precautions:
Anti-asthmatic drugs already in use should never be withdrawn abruptly when long-term treatment with Proasma is begun. This applies especially to systemic corticosteroids because of the possible existence of adrenocortical insufficiency in steroid-dependent patients: in such cases, recovery of normal pituitary-adrenal response to stress may take up to one year.

During the first few days of treatment with
Proasma the patient’s reactions maybe impaired. Care should therefore be exercised when driving a vehicle or operating machinery, etc.

A reversible fall in the thrombocyte count in patients receiving Proasma concomitantly with oral antidiabetic agents has been observed in rare cases. Thrombocyte counts should therefore be carried out in patients taking antidiabetics concomitantly.

In diabetic patients, the carbohydrate content of the syrup (5 ml = 4g carbohydrate) should be taken into consideration.

Although there is no evidence of any teratogenic effect. Proasma should be given to pregnant and nursing women only under compelling circumstances. Proasma should be kept out of reach of children.

Interactions:
Proasma may potentiate the effects of sedatives, hypnotics, antihistamines and alcohol.

Side effects:
Sedation and, in isolated cases, dry mouth and slight dizziness may occur at the beginning of treatment, but usually disappear spontaneously with continued medication. Weight gain has occasionally been reported.

Treatment of overdoseage :
The main symptoms of acute overdosage include :
drowsiness to severe sedation; confusion and disorientation; tachycardia and hypotension; convulsions, especially in children; hyperexeitability in children; reversible coma. Treatment should be symptomatic. If the drug has been taken recently, the stomach should be emptied. If necessary, symptomatic treatment and monitoring of the cardiovascular system; excitation and convulsions: short-acting barbiturates, benzodiazepines.

Store below 30°C in a dry place, protect from light.
Keep out of the reach of children.
Dosage as directed by the physician.
To be dispensed on the prescription of a registered medical practitioner only.