

LEAFLET

ZADIPRO SYRUP

Each 5ml syrup contains :-
Ketotifen fumarate equivalent to Ketotifen 1 mg

Product description :
Syrup : Clear, colourless syrup with peach flavour.

Pharmacodynamic:
Ketotifen is a non-bronchodilator anti-asthmatic drug with anti-anaphylactic and antihistaminic properties. Studies on the mode of action of ketotifen have shown the following properties of ketotifen which may contribute to its anti-asthmatic action :-
a) Inhibition of reactions to platelet-activating factor (PAF) which might be linked to its mast-cell stabilising activity or its capacity to modify expression of beta adrenoceptors.
b) Inhibition of the release of chemical mediators such as leukotrienes and histamines.
c) Functional antagonism of the bronchoconstriction effects of leukotrienes.
In addition, ketotifen exerts a powerful and sustained H1-receptor blocking activity which can be dissociated from its anti-anaphylactic properties.

Pharmacokinetics:
After oral administration, the absorption of ketotifen is almost complete. Bioavailability amounts to approximately 50% owing 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. About 1% of the substance is excreted unchanged in the urine within 48 hours and 60-70% as metabolites. The main metabolite is practically inactive ketotifen-N-glucuronide.
The pattern of metabolism in children is the same as in adults, but the clearance is higher in children. Children above 3 years therefore require the same daily dosage regimen as adults. On the basis of the kinetic data, it is recommended that children 6 months to 3 years should be given half of the adult dose.

Indication:
Ketotifen is a non-bronchodilator anti-asthmatic drug used in the prophylactic treatment of asthma associated with allergy, and may also be of benefit in intrinsic asthma. It may take several weeks of treatment to achieve the full therapeutic effect of ketotifen.
Ketotifen is also used for prevention and treatment of allergic reactions as it has the properties of an antihistamine.
Thus it can be used in improving and relieving conditions of allergic rhinitis, allergic bronchitis, allergic skin conditions and symptoms appearing in hay fever.

Recommended Dosage:
Adult : 1mg (5ml) - 2mg (10ml) 2 times daily. In patients susceptible to sedation, a progressive regimen is recommended during the 1st week of treatment commencing with 0.5mg (2.5ml) twice daily or 1mg (5ml) in the evening only and increasing to the full therapeutic dose. If necessary, the dosage may be increased up to 4mg (20ml) a day in 2 divided doses.
Syrup : Children above 3 years - 1mg (5ml) twice daily.
6 months to 3 years - 0.5mg (2.5ml) twice daily.

Route of Administration: Oral

Contraindications:
Contraindicated in patients with known hypersensitivity to ketotifen.

Warnings and Precautions:

Antiasthmatic drugs already in use should never be withdrawn abruptly when long - term treatment with ketotifen 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 a normal pituitary-adrenal response to stress may take up to 1 year. During the first few days of treatment with ketotifen, the patient's reactions may be impaired and they should therefore exercise care when driving a vehicle, operating machinery, etc.

It should not be used to treat acute asthma attacks.

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

Interactions with Other Medicaments:

Ketotifen may potentiate the effects of CNS depressant, alcohol and other antihistamines.
Concomitant administration of ketotifen with oral antidiabetic drug can lead to a reversible fall in thrombocyte count.

Pregnancy and Lactation:

Although there is no evidence of any teratogenic effect, ketotifen like all drugs, should be given to pregnant and nursing women only under compelling circumstances.

Side Effects:

Increased appetite and weight gain has been reported. Sedation and rarely, dry mouth or slight dizziness may occur at the beginning of treatment, but usually disappear spontaneously with continued medication. Occasionally, symptoms of CNS stimulation have been observed.

Symptoms and Treatment of Overdose :

The main symptoms of acute overdosage include: drowsiness to severe sedation, confusion and disorientation; tachycardia and hypotension; especially in children, hyperexcitability or convulsions; 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; if excitation or convulsions are present: short-acting barbiturates, benzodiazepines.

Effects on Ability to Drive and Use Machine:

During the first few days of treatment with ketotifen, the patient's reactions may be impaired and they should therefore exercise care when driving a vehicle, operating machinery, etc.

Storage Conditions:

Store at or below 30°C. Protect from light.

Pack Size: Syrup : A bottle of 100ml and 120ml.

Pack size (export only): Syrup : A bottle of 200ml, 250ml and 1 litre.

Shelf life: Bottle HDPE : 1.5 years
Bottle PET : 2 years

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
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SL344A-R5
Revision Date: 06/08/2025