Axcel®

KETOTIFEN

SYRUP

MAL19971379AZ

COMPOSITION:
Each 5ml contains
Ketotifen Hydrogen Fumarate
equivalent to Ketotifen 1mg

Sodium Benzoate 0.1% w/v as preservative.

PRESENTATION:
Orange coloured and orange flavoured syrup.

INDICATIONS:
Long-term prevention of bronchial asthma (all forms including mixed), allergic bronchitis, asthmatic symptoms associated with hay fever. Prevention and treatment of multisystem allergies, allergic rhinitis, allergic skin reactions and allergic conjunctivitis. Not effective in aborting established attacks of asthma.

PHARMACOLOGY:
Mechanism of Action:
Ketotifen is a nonbronchodilator, anti-asthmatic drug with marked antianaphylatic properties and a specific antihistaminic effect. Laboratory experiments both in vitro and in vivo have revealed the following properties of ketotifen which may contribute to its antiasthmatic activitiy:
a) Inhibition both of the acute broncho-constrictor response to PAF (Platelet Activating Factor) and of PAF induced airway hyperresponsiveness.
b) Inhibition of PAF-induced accumulation of eosinophils in the airway.
c) Inhibition of the release of such chemical mediators as histamine and leukotrienes.
d) Antagonism of acute bronchoconstriction due to leukotrienes.
e) Reversal and prevention of experimentally -induced tachyphylaxis to isoprenaline.
Ketotifen also exerts a powerful and sustained H1-receptor-blocking activitiy which can be clearly dissociated from its antianaphylactic properties.

Pharmacokinetics:
For oral administration, the absorption of ketotifen is almost complete.
Biovailability amounts to approximately 50% owing to a first-pass effect of about 50% in the liver. Maximal plasma concentrations are reached within 2 - 4 hrs. Protein binding is 75%. Ketotifen is eliminated biphasically, with a short half-life of 3 - 5 hrs and a longer one of 21 hrs. About 1% of the substance is excreted unchanged in the urine within 48 hrs and 60 - 70% as metabolites. The main metabolite is the 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 over 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 - 3 years should be given $^1/_2$ of the adult dose.

DOSAGE AND ADMINISTRATION:
For oral administration only.
5ml (1mg) twice daily with morning and evening meals.
In patients susceptible to sedation, a progressive regimen is recommended during the 1st week of treatment commencing with 2.5 - 5ml (0.5 - 1mg) at night and increasing to full therapeutic dose.
If necessary, the dosage may be increased up to 20ml (4mg) a day in divided doses.
Children:
6 months - 3 years : 2.5ml (0.5mg) twice daily.
Above 3 years : 5ml (1mg) twice daily.

CONTRAINDICATION:
Contraindicated in persons who are hypersensitive to the drug. A reversible fall in the thrombocyte count in patients receiving ketotifen with oral antidiabetic agents has been observed in rare cases. Thrombocyte counts should therefore be carried out in patients taking antidiabetics concomitantly.

PRECAUTION:
Antiasthmatic drugs already in use should never be withdrawn abruptly when long-term treatment with Ketotifen is begun. This applies especially to systemic cortico-steroids 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, the patients' reactions may be impaired and they should therefore exercise care when driving a vehicle, operation machine, etc. 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:
Sedation and, rarely, dry mouth or slight dizziness may occur at the begining of treatment, but usually disappear spontaneously with continued medication. Occasionally, symptoms of CNS stimulation have been observed. Weight gain has also been reported.

OVERDOSAGE & TREATMENT:
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.

STORAGE:
Keep container well closed. Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Available in 100ml PET bottle & 120ml amber glass bottle and 1L amber glass bottle (for export only).

Further information can be obtained from pharmacist, physician or the manufacturer.

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