Axcel®

LORATADINE

SYRUP

MAL20021421AZ

COMPOSITION:
Each 5ml contains
Loratadine 5mg

Sodium Benzoate 0.1% w/v as preservative.

PRESENTATION:
Colourless to light yellow colour syrup with peach flavour.

INDICATIONS:
Relief of symptoms associated with allergic rhinitis eg. sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching & burning, chronic urticaria and other allergic dermatologic disorders.

PHARMACOLOGY:
Mechanism of Action:
Loratadine is a long-acting tricyclic antihistamine with selective peripheral histamine H1-receptor antagonist activity. Approximately 80% of the total dose administered can be found equally distributed between urine and faeces in the form of metabolic products after 10 days.

Pharmacokinetics:
Loratadine rapidly absorbed from gastrointestinal tract after oral administration and peak plasma concentrations attained in about one hour and delay when administered with food. Loratadine undergoes extensive metabolism. The major metabolite, descarboethoxyloratadine are 12 and 18 hours respectively. About 98% of loratadine bound to plasma proteins. Loratadine and its metabolites been detected in breast milk, and are excreted in the urine and faeces.

DOSAGE AND ADMINISTRATION:
To be taken once daily.
Adults and children ≥12 years : 10ml (10mg) daily.
Children 2 - 12 years :
≥30kg : 10ml (10mg) daily.
<30kg : 5ml (5mg) daily.

CONTRAINDICATION:
Contraindicated in patients who are hypersensitive to any of its ingredients.

PRECAUTION:
Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of 5mg once daily or 10mg every other day is recommended.
Unsuitable for phenylketonurics.

Use in Pregnancy and Lactation:
Safe use of loratadine during pregnancy has not been established; therefore use only if potential benefit justifies potential risk to the fetus. Since loratadine is excreted in breast milk and because of the increased risk of loratadine for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the drug.

Use in Children:
Safety and efficacy of loratadine in children < 2 years have not yet been established.

SIDE EFFECTS:
The incidence of adverse effects associated with loratadine has been comparable to that of placebo. In controlled paediatric clinical trials, the incidence of treatment-related headache, sedation and nervousness, which were rarely reported events, was similar to placebo.

DRUG INTERACTIONS:
When administered concomitantly with alcohol, loratadine has no potential effects as measured by psychomotor performance studies. Increase in plasma concentrations of loratadine has been reported with concomitant use of ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic). Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed. Plasma concentration for loratadine may be increased by amprenavir.

OVERDOSAGE AND TREATMENT:
To date overdosage has not occurred with loratadine. A single acute ingestion of 160mg produced no adverse effects. In the event of overdosage, treatment which should be started immediately, is symptomatic and supportive. The patients should be induced to vomit even if emesis has occurred spontaneously. Pharmacologically-induced vomiting by the administration of ipecac syrup is a preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of 240 - 360ml of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in children. Following emesis, absorption of any drugs remaining in the stomach may be attempted by the administration of activated charcoal as a slurry with water. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. Physiologic saline solution is the lavage solution of choice, particularly in children. In adults, tap water can be used; however, as much as possible, the amount administered should be removed before the next instillation. Saline cathartics draw water into the bowel by osmosis and therefore, may be valuable for their action in rapid dilution of bowel content. Loratadine is not cleared by haemodialysis to any appreciable extent. After emergency treatment, the patient should continue to be medically monitored.

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 60ml & 100ml PET bottle.
Not all pack sizes may be marketed.

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

Product Registration Holder & Manufactured By :
KOTRA PHARMA
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