

Alaspan AM Tablets

COMPOSITION

Each uncoated tablet contains:

Loratadine USP 5 mg

Ambroxol Hydrochloride IP 60mg

DESCRIPTION

Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H₁-receptor antagonistic activity.

Ambroxol is a metabolite of bromhexine and is used as a mucolytic.

INDICATIONS

ALASPAN AM is indicated for the relief of symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis, acute and chronic disorders of respiratory tract associated with abnormal bronchial secretions, exacerbation of chronic bronchitis, asthmatic bronchitis and bronchial asthma.

DOSAGE AND ADMINISTRATION

For adults and children above 12 years: One tablet twice daily or as directed by the physician.

Use in Children

For children 2-12 years of age a syrup formulation of loratadine, ambroxol and guaifenesin will be available shortly.

The safety and efficacy of this combination in pediatric patients under the age of 2 years have not been established.

CONTRAINDICATIONS

Patients who have shown hypersensitivity or idiosyncrasy to the components of ALASPAN AM.

ADVERSE REACTIONS

Loratadine has no clinically significant sedative properties at the daily recommended dose of 10 mg. Most commonly reported side effects include fatigue, headache, somnolence, nervousness, dry mouth, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash. During the marketing of Loratadine tablet, alopecia, anaphylaxis, abnormal hepatic function, tachycardia and palpitations have been reported rarely.

Ambroxol can occasionally cause diarrhea, constipation, nausea, vomiting and sialorrhea. Transient rise in serum aminotransferase have also been reported. Other rare adverse events associated with the use of Ambroxol are dysuria, rhinorrhea, contact dermatitis, urticaria, exanthema, itching, pruritic erythema and vesicular eruptions near the nose, upper lips and cheeks, and pharyngeal soreness and spasm.

PRECAUTION

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

Efficacy of Loratadine in children younger than two years of age has not yet been established.

Ambroxol doses should be reduced in patents with severe renal or hepatic impairment, since in such patients elimination can be slowed down. Ambroxol should be given cautiously to patients with peptic ulceration.

USAGE DURING PREGNANCY AND LACTATION: Safe use of ALASPAN AM during pregnancy has not been established; therefore, use only if potential benefit justifies potential risk to fetus.

Special care is recommended for use of ambroxol during pregnancy, especially during the first 3 months of pregnancy. The benefits of ambroxol must be assessed against possible effects on your child.

Since loratadine is excreted in breast milk and because of the increased risk of antihistamines for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the drug. The benefits of ambroxol must be assessed against possible effects on your child.

DRUG INTERACTIONS

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

Increase in plasma concentrations of loratadine have been reported after concomitant use with 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.

Studies indicate that cimetidine at 300 mg four times daily for 10 days, which inhibits both enzymes, and erythromycin at 500 mg three times daily for 10 days or ketoconazole at 200 mg every 12 hours for 10 days, which inhibit P450, 3A4, each increased loratadine concentrations, although no adverse effects, clinical or electrocardiographic, were observed.

Ambroxol should not be taken simultaneously with antitussives (e.g. codeine) as the sputum, which has been liquefied by Ambroxol, might not be expectorated. Simultaneous use of Ambroxol with antibiotics like amoxycillin, cefuroxime, erythromycin, doxycycline leads to improved crossing of antibiotics into the lungs.

DRUG/LABORATORY TEST INTERACTIONS: Loratadine should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

OVERDOSAGE INFORMATION

Somnolence, tachycardia and headache have been reported with overdoses. A single acute ingestion of 160 mg produced no adverse effects. In the event of overdose, treatment, which should be started immediately, is symptomatic and supportive.

Treatment: Consider standard measures to remove any unabsorbed drug in the stomach, such as adsorption by activated charcoal administered as slurry with water. The administration of gastric lavage should be considered. Physiologic saline solution is the lavage solution of choice, particularly in children. In adults, tap water can be used; however, as much as possible of 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 hemodialysis to any appreciable extent. It is not known if loratadine is eliminated by peritoneal dialysis. After emergency treatment, the patient should continue to be medically monitored.

There are no reported cases of Ambroxol overdose, should it occur appropriate medical care should be given.

PRESENTATION

ALASPAN AM Tablets as a strip of 10 tablets

STORAGE

Store between 2°C and 30°C. Protect from moisture.

MANUFACTURED BY

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