

This insert contains basic prescribing information only.  
For more comprehensive information, a Professional Brochure is available to physicians on request.

## **ALASPAN\* Tablets & Syrup**

Brand of loratadine Long-Acting, Non-Sedating Antihistamine

**DESCRIPTION:** Each ALASPAN Tablet contains 10 mg micronized loratadine and the inactive ingredients corn starch, lactose and magnesium stearate.

Each 5 ml of ALASPAN\* Syrup contains 5 mg of micronized loratadine and the inactive ingredients propylene glycol; glycerin, citric acid monohydrate, sodium benzoate, sugar, peach flavour and purified water.

**ACTIONS:** Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H<sub>1</sub>- receptor antagonistic activity.

**INDICATIONS AND USAGE:** ALASPAN\* products are indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration.

ALASPAN\* products are also indicated for relief of symptoms and signs and chronic urticaria and other allergic dermatologic disorders.

### **DOSAGE AND ADMINISTRATION:**

*Adults and Children 12 years of age and over:*

ALASPAN\* Tablet: One tablet (10 mg) once daily

ALASPAN\* Syrup: Two teaspoonful (10ml) once daily

*Children 2 to 12 years of age:*

Body weight > 30 kg - 10 ml (10 mg) (two teaspoonful), ALASPAN\* Syrup once daily

Body weight > 30 kg - 5 ml (5 mg) (one teaspoonful), ALASPAN\* Syrup once daily

*Children 1 to 2 years of age*

One-half teaspoonful 2.5 ml (2.5 mg)

ALASPAN\* Syrup once daily

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

Increases in plasma concentrations of loratadine has 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 coadministered with caution until definitive interaction studies can be completed.

*Drug/Laboratory Test Interactions:* ALASPAN\* products should be discontinued approximately 48 hours prior to skin testing procedures since these drugs may prevent or diminish otherwise positive reactions to dental reactivity indicators.

**ADVERSE REACTIONS:** ALASPAN\* has no clinically significant sedative properties at the daily recommended dose of 10mg

Most commonly reported side effects include fatigue, headache, somnolence, dry mouth, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash.

During the marketing of ALASPAN\* tablets, alopecia, anaphylaxis and abnormal hepatic function have been reported rarely.

Similarly the incidence of adverse effects associated with ALASPAN\* Syrup has been comparable to that of placebo in controlled pediatric clinical trials, the incidence of treatment-related headache, sedation and nervousness, which were rarely reported events, was similar to that of placebo.

**CONTRAINDICATIONS:** ALASPAN\* products are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components.

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

Efficacy of ALASPAN\* has not yet been established in children younger than 2 years of age. However, the pharmacokinetic profile of loratadine in infants 1 to 2 years of age after administration of a single 2.5 mg dose of ALASPAN\* Syrup is similar to that in older children and adults.

**USAGE DURING PREGNANCY AND IN NURSING MOTHERS:** Safe use of ALASPAN\* products during pregnancy has not been established; therefore, use only if potential benefit justifies potential risk to fetus.

Since loratadine is excreted in breast milk and because of the increased risk of antihistamine for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the drug.

**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:* The patient 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 to 360 milliliters 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 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 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 in any appreciable extent. After emergency treatment, the patient should continue to be medically monitored.

**HOW SUPPLIED :** ALASPAN Tablets - Strip of 4 tablets  
ALASPAN Syrup - Bottle of 30 ml

**STORAGE :** Tablets - Store between 2° and 30°C  
Syrup - Store between 30°C

For additional information contact :



\* Tradename

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