

Lorin-NSA

(Loratadine)

لورین-این ایس اے

COMPOSITION

Each **Lorin-NSA** 10mg tablet contains 10mg of loratadine.Each 5ml **Lorin-NSA** syrup contains 5mg of loratadine.

PHARMACOLOGICAL PROPERTIES

Mode of action:

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

Human histamine skin wheal studies following single and repeated 10 mg oral doses of loratadine have shown that the drug exhibits an antihistaminic effect beginning within 1 to 3 hours, reaching a maximum at 8 to 12 hours, and lasting in excess of 24 hours. There was no evidence of tolerance to this effect after 28 days of dosing with loratadine. It does not readily cross the blood brain barrier.

Pharmacokinetics

Absorption: Loratadine was rapidly absorbed following oral administration of 10 mg tablets, with times to maximum concentration (T_{max}) of 1.3 hours for loratadine and 2.5 hours for its major active metabolite, descarboethoxyloratadine.

The plasma concentration profile of descarboethoxyloratadine for the tablet and syrup is comparable. Food increases the systemic bioavailability (AUC) of loratadine and descarboethoxyloratadine by approximately 40% and 15%, respectively. The time to peak plasma concentration (T_{max}) of loratadine and descarboethoxyloratadine was delayed by 1 hour. Peak plasma concentrations (C_{max}) were not affected by food.

Metabolism: Loratadine is metabolized to descarboethoxyloratadine predominantly by cytochrome P450 3A4 (CYP3A4) and, to a lesser extent, by cytochrome P450 2D6 (CYP2D6). In the presence of a CYP3A4 inhibitor ketoconazole, loratadine is metabolized to descarboethoxyloratadine predominantly by CYP2D6. Concurrent administration of loratadine with either ketoconazole, erythromycin (both CYP3A4 inhibitors), or cimetidine (CYP2D6 and CYP3A4 inhibitor) to healthy volunteers was associated with substantially increased plasma concentrations of loratadine.

Elimination: Approximately 80% of the total loratadine dose administered can be found equally distributed between urine and feces in the form of metabolic products within 10 days. The mean elimination half-life is 8.4 hours for loratadine and 28 hours for descarboethoxyloratadine. Loratadine and descarboethoxyloratadine reached steady state in most patients by approximately the fifth dosing day.

Special Populations:

Pediatric: The pharmacokinetic profile of loratadine in children in the 2 to 12 year age group is similar to that of adults.

Geriatric: The mean elimination half-lives for the geriatric subjects were 18.2 hours for loratadine and 17.5 hours for descarboethoxyloratadine.

Renal Impairment: The mean elimination half-lives of loratadine (7.6 hours) and descarboethoxyloratadine (23.9 hours) were not substantially different from that observed in normal subjects. Hemodialysis does not have an effect on the pharmacokinetics of loratadine or descarboethoxyloratadine in subjects with chronic renal impairment.

Hepatic Impairment: The elimination half-lives for loratadine and descarboethoxyloratadine were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

INDICATIONS

Loratadine is indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis and for the treatment of chronic idiopathic urticaria in patients 2 years of age or older.

DOSAGE AND ADMINISTRATION

Adults and children 6 years of age and over: The recommended dose of loratadine is one 10 mg tablet or 2 teaspoonfuls (10 mg) of syrup once daily.

Children 2 to 5 years of age: The recommended dose of loratadine Syrup is 5 mg (1 teaspoonful) once daily.

In adults and children 6 years of age and over with liver failure or renal insufficiency (GFR < 30 mL/min):

The starting dose should be 10 mg (one tablet or two teaspoonfuls) every other day. In children 2 to 5 years of age with liver failure or renal insufficiency, the starting dose should be 5 mg (one teaspoonful) every other day.

SIDE-EFFECTS

The most commonly reported side-effects are fatigue, dry mouth, allergic symptoms like rash, headache, gastrointestinal disturbances (eg. gastric upsets/nausea) and somnolence. The more uncommon side-effects include alopecia, anaphylaxis and an abnormal hepatic functioning. Less frequent incidences of abnormal hepatic function including hepatitis, jaundice and hepatic necrosis have been reported.

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 coadministered with caution until definitive interaction studies can be completed.

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.

PRECAUTIONS

General:

- Patients with liver impairment or renal insufficiency (GFR < 30 ml/min) should be given a lower initial dose (10 mg every other day).
- Loratadine lacks significant sedative effects. Patients should however be warned that a small number of individuals may experience sedation. Patients experiencing sedation or impaired concentration should be advised not to drive or perform complicated tasks. Sedation may be enhanced by the simultaneous intake of alcohol or other central nervous system depressants.

Pregnancy Category B: There was no evidence of animal teratogenicity. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, loratadine should be used during pregnancy only if clearly needed.

Nursing Mothers: Loratadine and its metabolite, descarboethoxyloratadine, pass easily into breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when loratadine is administered to a nursing woman.

Pediatric Use: The safety of loratadine Syrup at a daily dose of 10 mg has been demonstrated in 188 pediatric patients 6 to 12 years of age. The safety and tolerability of loratadine Syrup at a daily dose of 5 mg has been demonstrated in 60 pediatric patients 2 to 5 years of age. The safety and effectiveness of loratadine in children under 2 years of age have not been established.

OVERDOSE

In adults, somnolence, tachycardia, and headache have been reported with overdoses greater than 10 mg with the tablet formulation (40 mg-180 mg). Extrapyramidal signs and palpitations have been reported in children with overdoses of greater than 10 mg of loratadine Syrup. In the event of overdosage, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. Treatment of overdosage would reasonably consist of emesis (ipecac syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed with normal saline. Saline cathartics may also be of value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if loratadine is eliminated by peritoneal dialysis.

CONTRAINDICATIONS

Patients with known hypersensitivity to loratadine or any of the ingredients of **Lorin-NSA**.

PRESENTATION

Lorin-NSA tablet 10mg: 10's/pack

Lorin-NSA tablet 10mg: 30's/pack

Lorin-NSA syrup bottle: 30ml

Lorin-NSA syrup bottle: 60ml

Dosage:

As directed by the physician.

خوراک:

ڈاکٹر کی ہدایت کے مطابق۔

Instructions:

Store below 30°C.

Protect from sunlight & moisture.

Keep out of reach of children.

ہدایات:

دوا کو 30°C گری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

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Detailed prescribing information is available on request.

Manufactured by:
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An ISO Certified Company

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