

Loratin[®] Plus

Loratadine + Pseudoephedrine Sulfate

COMPOSITION

Loratin[®] Plus Tablet: Each bi-layer tablet contains Loratadine USP 10 mg as immediate release and Pseudoephedrine Sulfate USP 240 mg as extended release.

DESCRIPTION

Loratin[®] Plus tablet is a preparation of Loratadine and Pseudoephedrine Sulfate. Loratadine is a non-sedative histamine H₁receptor antagonist with anti-allergic properties. Loratadine is a long acting tricyclic anti-histamine with selective peripheral histamine H₁ receptor antagonistic activity and no central sedative or anti-cholinergic effect. Pseudoephedrine is a stereoisomer of Ephedrine , which has nasal and bronchial decongestant activity.

INDICATIONS

Loratin[®] Plus tablet is indicated for the relief of symptoms of seasonal and perennial allergic rhinitis **Loratin[®] Plus** tablet should be administered when both the antihistaminic properties of Loratadine and the nasal decongestant activity of Pseudoephedrine Sulfate are desired in patients 12 years of age and older. **Loratin[®] Plus** tablet also temporarily relieves runny nose, sneezing, itchy watery eyes, nasal congestion, itching of the nose or throat due to allergic rhinitis or other upper respiratory allergies, symptoms of common cold, nasal congestion & sinus pressure associated with sinusitis.

DOSAGE AND ADMINISTRATION

In adults and children 12 years of age and over: The recommended dose of Loratin[®] Plus tablet is once daily. As Loratin[®] Plus tablet contains Pseudoephedrine Sulfate which may cause agitation and insomnia as side effects, it is best recommended that Pseudoephedrine Sulfate should be administered in once daily formulation and be taken in the morning instead of night. Safety and effectiveness in children below the age of 12 years have not been established.

CONTRAINDICATIONS

Loratadine and Pseudoephedrine Sulfate combination tablet is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients. This product, due to its Pseudoephedrine Sulfate component, is contraindicated in patients with narrow angle glaucoma or urinary retention, and in patients receiving monoamine oxidase (MAO) inhibitor therapy or within fourteen (14) days of stopping such treatment. It is also contraindicated in patients with severe hypertension, severe coronary artery disease and in those who have shown hypersensitivity or idiosyncrasy to its components, to adrenergic agents, or to other drugs of similar chemical structures.

PRECAUTIONS

Loratadine and Pseudoephedrine Sulfate combination tablet should be used with caution in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment or prostatic hypertrophy. Central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension may be produced by sympathomimetic amines. It should

generally be avoided in patients with hepatic insufficiency. Patients with renal insufficiency (GFR<30 ml/min) should be given a lower initial dose (one tablet every other day).

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy Category B. There was no evidence of animal teratogenicity in reproduction studies. Loratadine and Pseudoephedrine Sulfate combination tablet should be used during pregnancy only if clearly needed.

Lactation: It is not known if this combination product is excreted in human milk.

However, both Loratadine and Pseudoephedrine Sulfate when administered alone passes into breast milk, therefore, a decision should be made whether to discontinue lactation or to discontinue loratadine and pseudoephedrine sulfate combination tablet, taking into account the importance of the drug to the mother.

DRUG INTERACTION

No specific interaction studies have been conducted with Loratadine and Pseudoephedrine Sulfate extended release tablets. However, loratadine (10 mg once daily) has been safely coadministered with therapeutic doses of erythromycin, cimetidine, and Ketoconazole in controlled clinical pharmacology studies.

Loratadine and Pseudoephedrine Sulfate combination tablet is contraindicated in patients taking monoamine oxidase inhibitors and for 2 weeks after stopping use of an MAO inhibitor. The antihypertensive effects of beta- adrenergic blocking agents, methyldopa, reserpine and veratrum alkaloids may be reduced by sympathomimetics. Increased ectopic pacemaker activity can occur when Pseudoephedrine is used concomitantly with digitalis.

OVERDOSE

In the event of overdose, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. Treatment of overdose 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.

SIDE EFFECTS

In general Loratadine and Pseudoephedrine Sulfate combination tablet is well tolerated. Clinical trials suggest a very low rate of adverse effects associated with its administration. Among the very few adverse effects, commonly reported are headache, nausea, dizziness, insomnia, dry mouth, somnolence, nervousness, fatigue, dyspepsia, anorexia, thirst etc. Serious adverse effects associated with the use of this drug are rare. Symptoms of central nervous system excitation may occur, including sleep disturbances and rarely, hallucinations have been reported.

PHARMACEUTICAL PRECAUTION

Store at a cool and dry place, away from light. Keep out of the reach of children.

HOW SUPPLIED

Loratin[®] Plus Tablet: Box containing 3x10's tablets in blister pack.

Manufactured by :



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