

Sinarest[®] *Levo* Tablets

Composition:

Each Sinarest Levo Tablet contains:

Phenylephrine 10 mg

Levocetirizine 2.5 mg

Pharmacokinetic properties:

Phenylephrine has low oral bioavailability owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver. When injected subcutaneously or intramuscularly it takes 10 to 15 minutes to act; subcutaneous and intramuscular injections are effective for up to about 1 hour and up to about 2 hours, respectively. Intravenous injections are effective for about 20 minutes. Systemic absorption follows topical application.

Levocetirizine is rapidly and extensively absorbed following oral administration. In adults, peak plasma concentrations are achieved 0.9 hour after administration of the oral tablet. Levocetirizine is poorly metabolized and undergo renal excretion.

Mechanism of Action

Phenylephrine decreases nasal congestion by acting on α_1 -adrenergic receptors in the arterioles of the nasal mucosa to produce constriction; this leads to decreased edema and increased drainage of the sinus cavities.

Levocetirizine is an inverse agonist that decreases activity at histamine H1 receptors. This in turn prevents the release of other allergy chemicals and increased blood supply to the area, and provides relief from the typical symptoms associated with seasonal and perennial allergic rhinitis. It does not prevent the actual release of histamine from mast cells.

Other pharmacodynamic properties:

Phenylephrine is a powerful vasoconstrictor. It is used as a nasal decongestant and cardiostimulant agent. Phenylephrine is a postsynaptic α_1 -receptor agonist with little effect on β -receptors of the heart. Parenteral administration of phenylephrine causes a rise in systolic and diastolic pressures, a slight decrease in cardiac output, and a considerable increase in peripheral resistance; most vascular beds are constricted, and renal, splanchnic, cutaneous, and limb blood flows are reduced while coronary blood flow is increased. Phenylephrine also causes pulmonary vessel constriction and subsequent increase in pulmonary arterial pressure. Vasoconstriction in the mucosa of the respiratory tract leads to decreased edema and increased drainage of sinus cavities.

Indication:



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For prompt, temporary relief of sneezing, itchy, watery eyes, itchy nose or throat, and runny nose caused in:

- Seasonal allergic rhinitis
- Perennial allergic rhinitis

Contraindication:

The use of Sinarest Levo Tablet is contraindicated in patients with:

- Hypersensitivity to any ingredient in this product.
- End-stage renal impairment of less than 10 mL/min creatinine clearance or patients undergoing haemodialysis.
- Overactive thyroid, high blood pressure or heart disease.
- Children 6 to 11 years of age with renal impairment

Drug Interaction:

Clinically significant drug interactions may occur on concomitant administration of Sinarest Levo Tablet with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents, and methyldopa, reserpine and veratrum alkaloids.

In vitro data indicate that levocetirizine is unlikely to produce pharmacokinetic interactions through inhibition or induction of hepatic drug metabolizing enzymes.

Adverse effects:

Sinarest Levo Tablet is well tolerated. Side effects are mild and often transient.

- Levocetirizine: The most common adverse reactions reported in clinical trials were: somnolence, nasopharyngitis, fatigue, dry mouth, and pharyngitis in subjects 12 years of age and older, and pyrexia, somnolence, cough, and epistaxis in children 6 to 12 years of age.
- Phenylephrine: As a class, sympathomimetic amines may also cause headaches, vomiting, diarrhea, insomnia, restlessness and palpitations. However, there have been few reports of these with normal doses of Phenylephrine.

Warnings and Precautions:

Sinarest Levo Tablet should be given with care to:

- Patients with impaired kidney or liver function and patients taking other drugs that affect the liver.
- Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Sinarest Levo Tablet is known.
- Patients with urinary retention, bladder-neck obstruction, or prostatic hypertrophy have the potential for exacerbation of urinary retention.
- Angle-closure glaucoma patients have the potential for increased intraocular pressure/precipitation of acute attack.



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- Patient receiving drugs for heart problems (including beta-blockers) or monoamine oxidase inhibitors (MAOIs) prescribed for depression.

Use in special population:

1. **Pediatric:** Do not exceed the recommended dose of 2.5 mg/day in children 6 to 11 years of age. The systemic exposure with the 5 mg dose is approximately twice that of adults. The safety and effectiveness of Sinarest-Levo in pediatric patients under 6 years of age have not been established.
2. **Geriatric:** Elderly population may be at greater risk for the side-effects.
3. **Liver impairment:** Safety in liver impairment patients has not been established.
4. **Renal failure:** Adjust the dose in patients 12 years of age and older with decreased renal function
5. **Pregnancy and lactation:** There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Sinarest Levo Tablet should be used during pregnancy only if clearly needed. As Levocetirizine is excreted in breast milk, Sinarest Levo Tablet is not recommended during breastfeeding.

Dosage:

- Adults & children 12 years: 1 tablet twice daily
- Children 6-11 years: ½ tablet twice daily

Presentation:

Sinarest-LP New Tablets are available in blister strips of 10 tablets.

Storage and handling:

Store below 30 °C in a dark and dry place.



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