

SINAREST-LP TABLETS

COMPOSITION

Each Tablet of **Sinarest LP** contains:

Levocetirizine	2.5 mg
Phenylephrine	10 mg
Paracetamol	500 mg
Caffeine	30 mg

PHARMACOLOGY

Levocetirizine is a non-sedating, third generation antihistamine. It blocks the effects of histamine, which causes itching, sneezing, runny nose, and watery eyes. Levocetirizine also has inbuilt nasal decongestant action. It has reduced anticholinergic and antiserotonin effects and therefore is preferred in patients with nasal congestion because it does not over dry nasal secretions.

Phenylephrine acts on alpha-receptors causing vasoconstriction of blood vessels in the lining of the nasal passages and sinuses. This leads to shrinkage in turbinate size thereby decreasing resistance to nasal airflow and relieving a blocked nose. Phenylephrine also reduces the production of mucus.

The actions of Levocetirizine and Phenylephrine compliment each other. While Levocetirizine works round the clock, Phenylephrine boosts the nasal decongestant action of Levocetirizine.

Paracetamol is a well-established analgesic and antipyretic agent. Despite its widespread use for several decades, the exact mode of action is still not fully understood. However, it is thought that it works by reducing the production of prostaglandins in the brain and spinal cord.

The body produces prostaglandins in response to injury and certain disease, which sensitize nerve endings, causing pain. Paracetamol reduces the production of these nerve-sensitizing prostaglandins and increases the pain threshold. Paracetamol reduces fever by affecting the hypothalamic heat-regulating center. Thus paracetamol in **Sinarest-LP** helps relieve aches, pain, sore throats and fever associated with rhinosinusitis, colds and flu.

Caffeine is a mild stimulant that helps reduce fatigue. Caffeine also enhances the analgesic effect of paracetamol.

The combination of levocetirizine, phenylephrine, paracetamol and caffeine in a single tablet of **Sinarest-LP** helps to relieve multiple symptoms of rhinosinusitis, colds and flu.

INDICATIONS

Rhinosinusitis, colds, flu.

DOSAGE

Adults and children >12 years: 1 tablet twice daily
Children 6-12 years: ½ tablet twice daily

CONTRAINDICATIONS

Sinarest-LP is not recommended for:

- ◆ Patients with known hypersensitivity to any ingredient in this product.
- ◆ Patients with end-stage renal impairment of less than 10 mL/min creatinine clearance or patients undergoing hemodialysis.
- ◆ Patients with overactive thyroid, high blood pressure or heart disease.
- ◆ Patients with severe hepatic dysfunction.

PRECAUTIONS

- ◆ **Sinarest-LP** should be given with care to patients with impaired kidney or liver function and patients taking other drugs that affect the liver.
- ◆ Dosage adjustment may be needed in patients 12 years of age and older with decreased renal function.
- ◆ Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and motor coordination such as operating machinery or driving a motor vehicle until their response to **Sinarest-LP** 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.

Pregnancy

There are, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, **Sinarest-LP** should be used during pregnancy only if clearly needed.

Lactation

As levocetirizine is excreted in breast milk, **Sinarest-LP** is not recommended during breastfeeding.

Pediatrics

Do not exceed the recommended dose of 2.5 mg/day in children 6 to 12 years of age. The systemic exposure with the 5 mg dose is approximately twice that of adults. The safety and effectiveness of **Sinarest-LP** in pediatric patients under 6 years of age have not been established.

WARNINGS

Sinarest-LP should not be taken with:

- ◆ Other medicines including those containing paracetamol for the relief of flu, colds or congestion.
- ◆ Drugs for heart problems (including beta-blockers) or monoamine oxidase inhibitors (MAOIs) prescribed for depression.

DRUG INTERACTIONS

Levocetirizine:

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

Phenylephrine:

- ◆ The co-administration of Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants and an indirect or mixed-acting sympathomimetic may result in a hypertensive crisis and hence such concomitant use is best avoided.
- ◆ Additionally sympathomimetics may reduce the efficacy of beta-blocking and anti-hypertensive drugs.

Paracetamol:

- ◆ Anticoagulant drugs (warfarin) - dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time
- ◆ Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide
- ◆ Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. antidepressants with anticholinergic properties, and narcotic analgesics
- ◆ Paracetamol may increase chloramphenicol concentrations
- ◆ The risk of paracetamol toxicity may be increased in patients receiving other hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- ◆ Paracetamol excretion may be affected when given with probenecid
- ◆ Colestyramine reduces the absorption of paracetamol if given within 1 hour.
- ◆ Regular use of paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

Caffeine:

- ◆ Smoking and drugs such as phenytoin, which induce hepatic microsomal metabolism result in an increase in caffeine clearance
- ◆ Drugs such as oral contraceptives reduce the rate of clearance by inhibiting caffeine metabolism.
- ◆ Caffeine elimination half-life has been reported to be increased and clearance decreased by the concomitant administration of ciprofloxacin.

ADVERSE EFFECTS

Sinarest-LP 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.

Paracetamol rarely causes any problems but allergic reactions, such as skin rash, occasionally occur. There have been very rare reports of blood disorders but these were not necessarily caused by paracetamol.

Caffeine may occasionally cause gastro-intestinal irritation and stimulation of the central nervous system.

PRESENTATION

Sinarest-LP is available in blister strips of 10 tablets