Sinarest® Syrup LP NEO

1. Composition

Levocetirizine	2.5mg
Ambroxol	15mg
Menthol	1mg

2. Dosage form and strength

Mango flavoured syrup available in pack of 60ml.

3. Clinical particulars

3.1 Therapeutic indication

Sinarest LP neo syrup is used in treatment of:

- In allergic productive cough
- In Maxillary Sinusitis

3.2 Posology and method of administration

Recommended oral dose of Sinarest LP neo syrup is:

- 2-6 years: 2.5ml twice a day.
- 6-12 years: 5ml twice a day.

3.3 Contraindication

Sinarest LP neo syrup is contraindicated in patients with:

- Known hypersensitivity for any ingredient of Sinarest LP neo syrup
- End stage renal disease
- Renal impairment

3.4 Special warnings and precautions for use

None.

3.5 Drug interactions

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

3.6 Use in special population

- Pediatric: As directed by doctor.
- Geriatric: No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.
- Liver impairment: Patients who only have impaired liver function should take the usual prescribed dose.
- Renal failure: Patients who have severe impairment of kidney function must not take Sinarest LP neo syrup.
- Pregnancy and lactation: Not recommended.

3.7 Effects on ability to drive and use machine

Use caution when driving or operating machinery until you know how this medicine affects you.

3.8 Undesirable effects

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.

Ambroxol can cause following side effects:

Common (may affect less than 1 in 10 patients)

- Taste disturbance
- Numbness in throat
- Nausea
- Numbness in mouth and tongue

Uncommon (may affect less than 1 in 100 patients)

- Diarrhoea
- Vomiting 4 / 5
- Indigestion
- Dry mouth
- Abdominal pain

Rare (may affect less than 1 in 1 000 patients)

- Hypersensitivity reactions
- Rash
- Urticaria

3.9 Overdose

There is limited experience of overdose with Sinarest LP neo syrup. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

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.

Ambroxol is a mucolytic agent. Excessive Nitric oxide (NO) is associated with inflammatory and some other disturbances of airways function. NO enhances the activation of soluble guanylate cyclase and cGMP accumulation. Ambroxol has been shown to inhibit the NO-dependent activation of soluble guanylate cyclase. It is also possible that the inhibition of NO-dependent activation of soluble guanylate cyclase can suppress the excessive mucus secretion; therefore it lowers the phlegm viscosity and improves the mucocilliary transport of bronchial secretions.

Menthol has a cooling effect on the throat. It has been suggested that the benefits of menthol may be to an effect on calcium channels of sensory nerves.

4.2 Pharmacodynamic properties

Ambroxol hydrochloride is a well-known and widely used secretolytic and secret motoric agent used for inflammatory diseases of the respiratory tract. Hence its pharmacodynamic model is generally well known, and there are no clinically relevant pharmacodynamic issues known at this point.

Menthol is a covalent organic compound made synthetically or obtained from peppermint or other mint oils. Menthol induces a cooling sensation on the skin upon inhalation, oral ingestion, or topical application by stimulating the cold-sensitive receptors expressed on the skin, without actually causing a drop in the skin temperature.

4.3 Pharmacokinetic properties

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.

The bioavailability of orally administered ambroxol HCl is high. Ambroxol HCl is highly protein-bound (80% to 90%) and is distributed widely and readily throughout the body. Ambroxol HCl is primarily cleared by metabolism and the resulting metabolites are eliminated renally. Unchanged ambroxol HCl was present in urine at less than 5% of the administered dose. Ambroxol HCl is predominantly metabolised by hepatic biotransformation via UGTs and to a lesser extent by CYP450. Ambroxol HCl is metabolised by multiple pathways in humans, but only one metabolite (DBAA) was determined to be major.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

24 months.

7.3 Storage and handling instructions

Store in cool and dry place.