

Sinarest[®]

Vapocap

1. Generic Name

Camphor, Chlorothymol, Eucalyptol, Menthol, Terpeneol

2. Qualitative and Quantitative composition

Each SINAREST Vapocap contains:

Camphor	25 mg
Chlorothymol	5 mg
Eucalyptol	125 mg
Menthol	65 mg
Terpineol	120 mg

3. Dosage form and strength

Capsules containing Camphor, Chlorothymol, Eucalyptol, Menthol, Terpeneol for inhalation.

4. Clinical particulars

4.1 Therapeutic indication

SINAREST Vapocap is indicated for prompt relief of symptoms of common cold, sinusitis, pharyngitis and other conditions accompanied by congestion of the upper respiratory tract.

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

The use of SINAREST Vapocap is contraindicated in patients with hypersensitivity to any ingredient of the formulation.

4.4 Special warnings and precautions for use

- Direct contact of SINAREST Vapocap with eyes and nostrils is to be strictly avoided.
- In case of exposure to the eyes or nostril, rinse/wash thoroughly with cold water.
- SINAREST Vapocap is not intended for oral administration.
- SINAREST Vapocap should be never exposed to flame or kept near microwave.

4.5 Drug interactions

NA.

4.6 Use in special population

- Pediatric: Use with caution.
- Geriatric: No data available.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: Doctor Consultation is recommended.

4.7 Effects on ability to drive and use machine

NA.

4.8 Undesirable effects

No adverse events have been reported with the use of SINAREST Vapocap.

4.9 Overdose

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

5. Pharmacological properties

5.1 Mechanism of action

SINAREST Vapocap contains aromatic ingredients that SINAREST Vapocap provides relief from various respiratory ailments.

- Camphor applied externally acts as a rubefacient and mild analgesic. It is also a principal ingredient of many nasal decongestants for inhalation.
- Menthol is chiefly used to relieve symptoms of bronchitis, sinusitis and similar conditions. For this purpose, it may be used as an inhalation or as an ointment with camphor and eucalyptus oil for application to the chest and nostrils.
- Eucalyptus oil has been used as an inhalation often with other volatile substances. Eucalyptol kills bacteria and eases breathing difficulties in people with croup, asthma and bronchitis. It is also used externally for chest congestion, to ease aches and pains, and as a deodorant.
- Terpineol has anti-infective properties.
- Chlorothymol is a multipurpose phenolic antiseptic. It finds special use in symptomatic relief from common cold.

5.2 Pharmacodynamic properties

Menthol is a covalent organic compound made synthetically or obtained from peppermint or other mint oils. Menthol's ability to chemically trigger cold-sensitive receptors in the skin is responsible for the well-known cooling sensation that it provokes when inhaled, eaten, or applied to the skin. It should be noted that menthol does not cause an actual drop in temperature.

5.3 Pharmacokinetic properties

Camphor is readily absorbed from all administration sites. It is hydroxylated in the liver to yield hydroxyl camphor metabolites which are then conjugated with glucuronic acid and excreted in the urine. Camphor crosses the placenta.

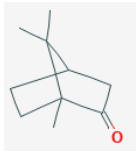
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

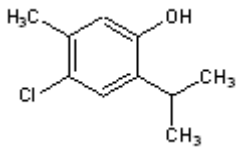
7. Description

Camphor chemical name is 1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one and its structure is



Its empirical formula is $C_{10}H_{16}O$ and its molecular weight is 152.23 g/mol.

Chlorothymol chemical name 4-chloro-5-methyl-2-propan-2-ylphenol and its structure is



Its empirical formula is $C_{10}H_{13}ClO$ and its molecular weight is 184.665 g/mol.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

SINAREST Vapocap are available in a pack of 10 Vapocaps.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by Softech Pharma Pvt. Ltd

11. Details of permission or license number with date

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12. Date of revision: January 2021