

Sinarest-S[®]

1. Generic Name

Sodium chloride

2. Qualitative and Quantitative composition

Sodium Chloride 0.74%w/v.

3. Dosage form and strength

Drops of sodium chloride 0.74% for nasal administration.

4. Clinical particulars

4.1 Therapeutic indication

Sinarest-S nasal drops is indicated in blocked, dry, crusty and itchy nose.

4.2 Posology and method of administration

Tilt head back; apply 2 to 6 drops of Sinarest-S nasal solution in each nostril every 2 hours as needed or as directed by doctor.

4.3 Contraindication

There no contraindications for Sinarest-S nasal drops.

4.4 Special warnings and precautions for use

There are no specific precautions for Sinarest-S nasal drops. It can be used as often required.

4.5 Drug interactions

There no interactions for Sinarest-S nasal drops.

4.6 Use in special population

- Pediatric: safe

- Geriatric: safe
- Liver impairment: safe
- Renal failure: safe
- Pregnancy and lactation: safe

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Sinarest S nasal drops is known.

4.8 Undesirable effects

There are no contraindications for Sinarest-S nasal drops.

4.9 Overdose

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

5. Pharmacological properties

5.1 Mechanism of action

- Sinarest-S nasal drops is effective in restoring moisture to nasal membranes affected by dryness due to climate, respiratory infections, travel, oxygen therapy, overuse of nasal decongestants, and hormonal changes caused by pregnancy.
- It aids in eliminating congestion by washing away mucus and allergens from the nose and sinuses.
- It is soothing, non-irritating solution, which is formulated to be compatible with nasal membranes to prevent the stinging, burning and irritation of delicate nasal tissue.
- Solution is buffered to a neutral pH to loosen and thin congestion caused by colds or allergies. Restores moisture to dry nasal membranes.

5.2 Pharmacodynamic properties

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

5.3 Pharmacokinetic properties

Sodium chloride is well absorbed from the gastrointestinal tract. Excess sodium is mainly excreted by the kidney, and small amounts are lost in the faeces and sweat. A 0.9% solution in water is iso-osmotic, and thus in most cases isotonic with serum and lacrimal secretions. Nasal drops of sodium chloride 0.9% are used to relieve nasal congestion.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Sodium chloride chemical structure is NaCl and its molecular weight is 58.44 g/mol.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

Sinarest-S nasal drops is available in 15ml plastic bottle with in build nozzle.

8.4 Storage and handling instructions

Store 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

CENTAUR PHARMACEUTICALS PVT. LTD.

11. Details of permission or license number with date

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