1. **Generic Name**

Oxymetazoline, Sorbitol

2. **Qualitative and Quantitative composition**

Oxymetazoline……0.05% w/v

Sorbitol……2% w/v

3. **Dosage form and strength**

Nasal solution containing Oxymetazoline 0.05%

4. **Clinical particulars**

4.1 Therapeutic indication

Relief of nasal congestion due to a cold, upper respiratory allergies or sinusitis.

4.2 Posology and method of administration

2-3 times a day or as directed by physician.

4.3 Contraindication

The use of Sinarest Nasal spray is contraindicated in patients with known hypersensitivity to its ingredients.

4.4 Special warnings and precautions for use

Sinarest Nasal spray should be administered with caution in patients with hypertension, coronary artery disease, hyperthyroidism or diabetes mellitus.

As with formulations, the use of the same packing of SINAREST Nasal spray by more than one person may spread infection.

If used over a longer period Sinarest nasal spray may cause a blocked nose. It is not recommended to use for longer than one week. Contact your doctor if symptoms worsen or do not improve after 7 days.

4.5 Drug interactions

Monoamine Oxidase Inhibitors: Use of Sinarest nasal spray in combination with monoamine oxidase inhibitors (MAOIs), nonselective beta adrenergic antagonists, or tricyclic antidepressants may cause hypertension and is not recommended. Alternative anesthetic agents should be chosen for patients who cannot discontinue use of MAOIs, nonselective beta adrenergic antagonists, or tricyclic antidepressants.

Oxymetazoline-containing Products: Use of Sinarest nasal spray with other products containing oxymetazoline may increase risk of hypertension, bradycardia, and other adverse events associated with oxymetazoline. Discontinue use 24 hours prior to administration of Sinarest nasal spray.

Intranasal Products: Oxymetazoline has been known to slow the rate, but not affect the extent of absorption of concomitantly administered intranasal products. Do not administer other intranasal products with Sinarest nasal spray.

4.6 Use in special population

- Pediatric: The safety of use of SINAREST Nasal Spray in children has not been established.
- Geriatric: The safety of use of SINAREST Nasal Spray in elderly patients has not been established.
- Liver impairment: The safety of use of SINAREST Nasal Spray has not been established.
- Renal failure: The safety of use of SINAREST Nasal Spray has not been established.

- Pregnancy and lactation: The safety of use of SINAREST Nasal Spray in pregnancy and lactation has not been established. Therefore, use only when clearly indicated.

4.7 Effects on ability to drive and use machine

No data available.

4.8 Undesirable effects

Sinarest Nasal spray may occasionally cause local stinging or burning sensation, sneezing, and dryness of the mouth and throat. Prolonged use may cause rebound congestion and drug induced rhinitis. Some of the rare adverse effects are anxiety, fatigue, irritability, disturbed sleep in children, rapid heart-beat, palpitations, raised blood pressure, , swelling of the nasal lining, headache, nausea, flushing, rash and visual disturbances.

4.9 Overdose

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

5. Pharmacological properties

5.1 Mechanism of action

Oxymetazoline is a direct acting sympathomimetic amine, which acts on alpha-adrenergic receptors in the arterioles of the conjunctiva and nasal mucosa. It produces vasoconstriction, resulting in decreased conjunctival congestion in ophthalmic. In nasal it produces constriction, resulting in decreased blood flow and decreased nasal congestion.

Sorbitol prevents dehydration thus enhances miniaturisation of nasal mucosa.

5.2 Pharmacodynamic properties

Oxymetazoline a adrenergic alpha-agonists, direct acting sympathomimetic used as a vasoconstrictor to relieve nasal congestion The sympathomimetic action of Oxymetazoline constricts the smaller arterioles of the nasal passages, producing a prolonged (up to 12 hours), gentle and decongesting effect. Oxymetazoline elicits relief of conjunctival

hyperaemia by causing vasoconstriction of superficial conjunctival blood vessels. The drug's action has been demonstrated in acute allergic conjunctivitis and in chemical (chloride) conjunctivitis.

Sorbitol exerts its laxative effect by drawing water into the large intestine, thereby stimulating bowel movements.

5.3 Pharmacokinetic properties

Sorbitol is poorly absorbed from the gastrointestinal tract after oral or rectal use. It is metabolised mainly in the liver, to fructose, a reaction catalysed by the enzyme sorbitol dehydrogenase. Some sorbitol may be converted directly to glucose by the enzyme aldose reductase.

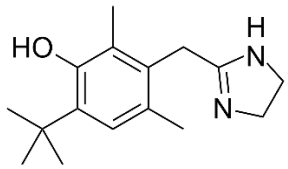
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Oxymetazoline is in a class of medications called nasal decongestants. Its chemical formula is 6-*tert*-butyl-3-(4,5-dihydro-1*H*-imidazol-2-ylmethyl)-2,4-dimethylphenol and its chemical structure:



Its empirical formula is $C_{16}H_{24}N_2O$and its molecular weight is 260.37 g/mol.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

Sinarest Nasal spray is available in 10 ml bottle

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

CENTAUR PHARMACEUTICALS PVT. LTD.

11. Details of permission or license number with date

158(230)/MFG/DFDA/2020/1967 dated. 16.10.2020 for domestic.

12. Date of revision:

January 2022