Sinarest®-PD

NASAL DROPS

1. **Generic Name**

Oxymetazoline

2. **Qualitative and Quantitative composition**

Oxymetazoline……0.025% w/v

3. **Dosage form and strength**

Nasal drops of Oxymetazoline 0.025%

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

As directed by physician.

4.3 Contraindication

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

4.4 Special warnings and precautions for use

Sinarest PD Nasal drops 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 PD Nasal drops by more than one person may spread infection.

4.5 Drug interactions

Clinically significant drug interactions may occur on concomitant administration of Sinarest PD Nasal drops with monoamine oxidase inhibitors, tricyclic antidepressants, b-adrenergic agents, and methyldopa, reserpine and veratrum alkaloids.

4.6 Use in special population

- Pediatric: safe.
- Geriatric: The safety of use of Sinarest PD Nasal drops in elderly patients has not been established.
- Liver impairment: The safety of use of Sinarest PD Nasal drops has not been established.
- Renal failure: The safety of use of Sinarest PD Nasal drops has not been established.
- Pregnancy and lactation: The safety of use of Sinarest PD Nasal drops in pregnancy and lactation has not been established. Therefore, use only when clearly indicated.

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 –PD nasal drops is known.

4.8 Undesirable effects

Sinarest PD Nasal drops 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.

4.9 Overdose

There is limited experience of overdose with Sinarest PD nasal drops. 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.

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.

5.3 Pharmacokinetic properties

Not available.

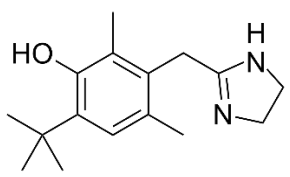
6. Nonclinical properties

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 PD nasal drops 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 and DCI Pharmaceuticals.

11. Details of permission or license number with date

158(257)/MFG/DFDA/2004/769 dated. 10.06.2004 for export.

12. Date of revision:

January 2021