

Sinarest[®]-PD

NASAL DROPS

1. Composition

Oxymetazoline 0.025%w/v

2. Dosage form and strength

SINAREST-PD Nasal Drops is available in 10 ml bottle with calibrated dropper

3. Clinical particulars

3.1 Therapeutic indication

SINAREST-PD Nasal Drops is indicated for relief of nasal congestion due to a cold, upper respiratory allergies or sinusitis.

3.2 Posology and method of administration

As directed by physician.

3.3 Contraindication

The use of SINAREST-PD Nasal Drops is contraindicated in patients with known hypersensitivity to its ingredient.

3.4 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.

3.5 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, methyldopa, reserpine and veratrum alkaloids.

3.6 Use in special population

- Paediatric: Safe.
- Geriatric: The safety of use of SINAREST –PD nasal drops has not been established.
- Liver impairment: The safety of use of SINAREST –PD nasal drops has not been established.



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- 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 has not been established.

3.7 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.

3.8 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.

3.9 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.

4. Pharmacological properties

4.1 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 eyes. In nose, it produces constriction, resulting in decreased blood flow and decreased nasal congestion.

4.2 Pharmacodynamic properties

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

4.3 Pharmacokinetic properties

Not available.

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

36 months.

7.3 Storage and handling instructions

Store in cool and dry place.



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