1. Composition

Oxymetazoline	0.025%w/v
Sorbitol	2%w/v

2. Dosage form and strength

Sinarest Nasal spray is available in 10 ml bottle with calibrated dropper.

3. Clinical particulars

3.1 Therapeutic indication

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 Nasal spray is contraindicated in patients with known hypersensitivity to its ingredients.

3.4 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.

3.5 Drug interactions

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

3.6 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.

3.7 Effects on ability to drive and use machine

No data available.

3.8 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.

3.9 Overdose

There is limited experience of overdose with Sinarest new Tablets. 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 ophthalmic. In nasal it produces constriction, resulting in decreased blood flow and decreased nasal congestion.

Sorbitol prevents dehydration thus enhances miniaturisation of nasal mucosa.

4.2 Pharmacodynamics 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.

4.3 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.

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.