SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

SINAREST 0,025 % nasal spray, solution

SINAREST 0,05 % nasal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of SINAREST 0,025 % solution contains 0,25 mg oxymetazoline hydrochloride.

Each 1 mL of SINAREST 0,05 % solution contains 0,50 mg oxymetazoline hydrochloride.

Excipient with known effect:

Preservative: Benzalkonium chloride 0,0055 % *m/v*

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

Colourless, clear solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

SINAREST is used for the temporary relief of nasal congestion in colds and influenza, hay fever, allergic rhinitis, other upper respiratory allergies, post-nasal drip and sinusitis.

4.2 Posology and method of administration

SINAREST 0,025 % for children 2 to 6 years of age (with adult supervision):

How to use SINAREST 0,025 %:

- Place the tip of the nozzle in one nostril without completely occluding the nostril.
- Bend head slightly forward and spray 2 to 3 times while sniffing briskly, not more than every 10 to 12 hours.
- Treat the other nostril in the same way.
- Do not exceed 2 applications in any 24-hour period.
- Wipe nozzle clean after each use.

Do not exceed the recommended dosage or use for longer than 5 days.

SINAREST 0,05 % for adults and children over 6 years of age:

How to use SINAREST 0,05 %:

- Place the tip of the nozzle in one nostril without completely occluding the nostril.
- Bend head slightly forward and spray 1 to 2 times while sniffing briskly, not more than every 10 to 12 hours.
- Treat the other nostril in the same way.
- Do not exceed 2 applications in any 24-hour period.
- Wipe nozzle clean after each use.

Do not exceed the recommended dosage or use for longer than 5 days.

4.3 Contraindications

SINAREST is contraindicated in:

- Hypersensitivity to oxymetazoline hydrochloride or to any of the ingredients of SINAREST listed in section 6.1.
- Patients where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- Patients receiving monoamine oxidase inhibitors, or within 14 days of its termination.
- Patients after transsphenoidal hypophysectomy.
- Patients with porphyria.
- Patients with severe hypertension or phaeochromocytoma.

4.4 Special warnings and precautions for use

- SINAREST 0,05 % is not recommended for children under 6 years of age.
- SINAREST should not be used for more than 5 days. If symptoms persist, a doctor should be consulted.
- Prolonged use or excessive application of SINAREST to the nasal mucosa may lead to rebound congestion and rhinorrhoea.
- Use with caution in patients with cardiovascular disorders (especially cardiac dysrhythmias, ischaemic heart disease, tachycardia or hypertension).

- Use with caution in patients with an occlusive vascular disease who are at an increased risk of peripheral ischaemia.
- Caution is advised in patients with hyperthyroidism, who may be at increased risk of effects on the heart (elevated thyroid hormone concentrations may also enhance adrenoceptor sensitivity).
- Use with caution in patients suffering from aneurysms and diabetes mellitus.
- Diabetic and elderly patients have a high incidence of atherosclerotic disease and may also be at higher risk.
- Use with caution in patients with closed-angle glaucoma.
- Patients with prostate disorders (such as prostatic hypertrophy) should use SINAREST with caution as they may be at risk of urinary retention.
- SINAREST should not be used by more than one person as it may spread infection.
- Children may be especially sensitive to the effects of SINAREST therefore caution should be used when administering to children.
- SINAREST contains benzalkonium chloride as preservative. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

4.5 Interaction with other medicines and other forms of interaction

- Severe hypertension may occur when used concomitantly with monoamine oxidase inhibitors (MAOIs) and the combined use is contraindicated (see section 4.3).
- Increased cardiac effects may occur with medicines that increase the sensitivity of the myocardium to beta1 agonists. Take special care when using SINAREST together with cardiac glycosides (such as digoxin) and antidysrhythmics (such as quinidine).
- Caution is required when SINAREST is used in combination with thyroid hormones.
- Use SINAREST with caution in combination with antihypertensive medicines or medicines that cause hypotension, particularly those whose action involves the sympathetic nervous system.
- Interactions with alpha- and beta-blockers may be complex and can produce a hypertensive crisis.
- The antihypotensive effects of adrenergic neurone blockers (such as guanethidine, reserpine, alpha-methyldopa) may be reversed and may result in hypertension.
- Tricyclic antidepressants block the inactivation of epinephrine (adrenaline) and norepinephrine (noradrenaline) by uptake into the nerve endings and as a result hypertension and dysrhythmias may occur.

- Maprotiline may potentiate the pressor effects of oxymetazoline.
- The effect of central nervous system (CNS) stimulants may be potentiated, while the vasoconstrictor and vasopressor effects of alpha agonists may be enhanced by medicines with similar effects, such as ergot alkaloids or oxytocin.
- SINAREST should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics, as thy may induce ventricular fibrillation.
- Inhalation anaesthetics may increase the risk of dysrhythmias when used in combination with SINAREST.
- Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian medicines, such as bromocriptine.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

As SINAREST may cause dizziness, light-headedness and hypotension, it is recommended that driving and operating machinery be avoided until it is known how SINAREST affects the patient.

4.8 Undesirable effects

Immune system disorders:

Frequency unknown: Hypersensitivity.

Metabolism and nutrition disorders:

Frequency unknown: Altered metabolism (including disturbances of glucose metabolism).

Psychiatric disorders:

Less frequent: Anxiety, irritability, nervousness, restlessness.

Frequency unknown: Agitation, psychotic states, fear.

Nervous system disorders:

Less frequent: Headache, insomnia, tremor.

Frequency unknown: Confusion, pain, dizziness, light-headedness, drowsiness, trembling, hallucinations (particularly in children).

Eye disorders:

Less frequent: Eye irritation, discomfort or redness.

Frequency unknown: Blurred vision.

Cardiac disorders:

Less frequent: Palpitations, tachycardia.

Frequency unknown: Ventricular dysrhythmias, anginal pain, cardiac arrest, bradycardia.

Vascular disorders:

Frequency unknown: Vasoconstriction, hypertension, hypotension, cerebral haemorrhage, reactive hyperaemia.

Respiratory, thoracic and mediastinal disorders:

Less frequent: Sneezing.

Frequency unknown: Pulmonary oedema, increased nasal discharge, dyspnoea, increase in stuffy nose, nasal dryness, nasal irritation, throat irritation, rebound congestion.

Gastrointestinal disorders:

Less frequent: Dryness of the mouth and throat, nausea.

Frequency unknown: Vomiting, reduced appetite, thirst.

Skin and subcutaneous tissue disorders:

Frequency unknown: Increased sweating, unusual paleness, piloerection, rash.

Renal and urinary disorders:

Frequency unknown: Difficult or painful urination, urinary retention.

General disorders and administration site conditions:

Less frequent: Flushing

Frequency unknown: Local stinging, burning, hypersalivation, cold extremities, weakness, fainting, appetite reduction.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of SINAREST is important. It allows continued monitoring of the benefit/risk balance of SINAREST. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

See section 4.8.

Systemic administration causes sedation, dry mouth and sweating. Alpha-adrenergic blockade may be necessary for severe hypertension. Symptoms of moderate or severe overdose can be mydriasis, nausea, cyanosis, fever, spasms, tachycardia, cardiac arrhythmia, cardiac arrest, hypertension, oedema of the lungs, dyspnoea, psychic disturbance. The inhibition of functions of the central nervous system such as somnolence, lowering of the body temperature, bradycardia, shock like hypotension, apnoea and loss of consciousness is also possible.

Paediatric population:

Clinical manifestation includes CNS signs and symptoms: convulsion and coma, hallucinations, bradycardia, apnoea, hypertension changing into hypotension.

Withdrawal or reduction of dosage may be required.

Treatment

A nonselective alphalytic such as phentolamine may be administered to depress the increased blood pressure. Intubation and artificial respiration may be necessary in serious cases. In the case of moderate or severe inadvertent oral consumption standard methods to remove unabsorbed medicines are indicated.

Further treatment is supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 16.1 Nasal decongestants.

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use. Sympathomimetics, plain.

ATC code: R01AA05.

Oxymetazoline hydrochloride is a direct acting sympathomimetic medicine with alpha-adrenergic activity. It is a vasoconstrictor which reduces swelling and congestion when applied to the nasal mucous membranes.

Oxymetazoline hydrochloride acts within a few minutes and the effect lasts for up to 12 hours.

5.2 Pharmacokinetic properties

Oxymetazoline hydrochloride is delivered directly to the nasal mucosa, where it exerts a local vasoconstriction effect. Due to its topical, local, and rapid action, oxymetazoline hydrochloride has a very low potential for systemic absorption. However, potential systemic exposure with higher doses and longer durations of use could lead to systemic side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dihydrate

Sodium dihydrogen phosphate dihydrate

Sodium hydroxide

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Keep container tightly closed when not in use.

The product should be discarded if the solution becomes discoloured.

6.5 Nature and contents of container

White plastic bottle (HDPE) with a mechanical spraying device. Nasal spray pump consisting of a nasal actuator with white screw closure/protection cap and housing with basic pump system. Each bottle contains 10 mL of solution. Each carton contains 1 bottle.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iPharma (Pty) Ltd

124 Elevation Avenue, Randjesfontein

Midrand, 1683, South Africa

8 REGISTRATION NUMBERS

SINAREST 0,025 %: 44/16.1/0745

SINAREST 0,05 %: 44/16.1/0746

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 June 2014

10 DATE OF REVISION OF THE TEXT

20 January 2023