Scheduling Status:
S1

SINAREST 0,025 % nasal spray, solution

SINAREST 0,05 % nasal spray, solution

Oxymetazoline hydrochloride

Read all of this leaflet carefully because it contains important information for you.

SINAREST is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SINAREST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINAREST with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after five days.

What is in this leaflet:

1. What SINAREST is and what it is used for
2. What you need to know before you use SINAREST
3. How to use SINAREST
4. Possible side effects
5. How to store SINAREST
6. Contents of the pack and other information

1. What SINAREST is and what it is used for:

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.

2. What you need to know before you use SINAREST:

Do not use SINAREST:

- If you are hypersensitive (allergic) to oxymetazoline hydrochloride or to any of the other ingredients of SINAREST (listed in section 6).

- If you have inflammation in your nose or experiencing a dry nose or the formation of crusting that can fill the nose (rhinitis sicca).
- If you are using medicine to treat depression (specifically monoamine oxidase inhibitors) or have stopped your treatment within the last 14 days.
- If you have narrow-angle glaucoma (increased pressure in eyes).
- After having a surgical procedure removing small tumours or glands through your nose cavity.
- If you have a disorder called porphyria.
- If you have a present heart disease or suffer from cardiac failure that is causing troubled breathing, wheezing or coughing.
- If you have severe high blood pressure.
- If you have a tumour on the adrenal gland called a phaeochromocytoma.

Warnings and precautions:

Tell your doctor:

- If you have any heart disorder or high blood pressure (hypertension).
- If you have an overactive thyroid gland.
- If you suffer from aneurysms, which is an abnormal bulge or ballooning in the wall of a blood vessel, causing the vessel to rupture.
- If you have diabetes (high blood sugar).
- If you are an elderly person.
- If you have a prostate disorder, such as an enlarged prostate gland.

Take special care with SINAREST:

- If your symptoms continue for more than 5 days while using SINAREST consult your doctor immediately. Do not use SINAREST for longer than 5 days. Using SINAREST for a long period may lead to rebound congestion (abnormal swelling and enlargement of the nasal passages, which blocks the nasal airway completely and causes extreme discomfort). Please consult your doctor if symptoms persist.
- Do not share SINAREST with other people, as it may spread the infection.
- Use SINAREST with caution in children, as they may be especially sensitive to the effects.

Children and adolescents

SINAREST 0,05 % is not recommended for children under 6 years of age.

SINAREST 0,025 % is indicated for use in children aged 2 to 6 years, under adult supervision.

Other medicines and SINAREST

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take the following medicines in combination with SINAREST:

- Monoamine oxidase inhibitors (MAOIs) used in the treatment of Parkinson's disease and depression – do not use SINAREST if you have taken MAOIs during the last 14 days

Tell your doctor if you are using:

- Tricyclic antidepressants (such as clomipramine, imipramine and amitriptyline), or maprotiline used in the treatment of depression.
- Medicines used to increase the sensitivity of the heart muscle and to stabilise the rhythm of the heart. This includes medicines such as digoxin (a cardiac glycoside), amiodarone, disopyramide, propafenone, flecainide, quinidine and beta-blockers.
- Thyroid hormones (used to treat thyroid gland disorders).
- Antihypertensive medicines (such as guanethidine, reserpine or alpha-methyldopa) used to lower high blood pressure.
- Ergot alkaloids (used to treat migraines or very severe headaches).
- Oxytocin (used to induce labour in women having weak or no contractions).
- Parkinson's disease medicine (such as bromocriptine).

Before receiving inhalation anaesthesia (such as cyclopropane, halothane or halogenated anaesthetics), tell your doctor that you are using SINAREST.

SINAREST with food or drink:

SINAREST may be used with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using SINAREST.

Driving and using machines

SINAREST will most likely not make you drowsy or impair your ability to drive and use machinery, but take care if you feel dizzy, tired or drowsy while using SINAREST.

Do not drive or use machinery until you are sure that SINAREST does not affect your ability to drive or use machinery.

SINAREST contains benzalkonium chloride (as preservative):

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use SINAREST:

Always use SINAREST exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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 blocking the nostril.
- Bend head slightly forward and spray 2 to 3 times while sniffing in at the same time, not more than every 10 to 12 hours.
- Do this again with the other nostril.
- Do not use more than twice in 1 day.
- Wipe the nozzle clean after each use.

Do not use more often than what is recommended for your child or 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 blocking the nostril.
- Bend your head slightly forward and spray 1 to 2 times while sniffing in at the same time, not more than every 10 to 12 hours.
- Do this again with the other nostril.
- Do not use more than twice in 1 day.
- Wipe the nozzle clean after each use.

Do not use more often than what is recommended for you or for longer than 5 days.

If you have any questions about the proper dose of SINAREST, ask your pharmacist or doctor.

If you use more SINAREST than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining product with you, so that the doctor knows what you have taken.

If you forget to use SINAREST:

Do not use a double dose to make up for forgotten individual doses.

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and use SINAREST at the next regular scheduled time. **Do not use a double dose to make up the missed dose.**

4. Possible side effects:

SINAREST can have side effects.

Not all side effects reported for SINAREST are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using SINAREST, please consult your health care provider for advice.

If any of the following happens, stop using SINAREST and tell your doctor or go to the casualty department at your nearest hospital:

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINAREST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effect:

- Fast, irregular or pounding heartbeat.

Frequency not known:

- Chest pain (anginal pain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Headache.
- Nervousness.
- Trembling.
- Difficulty falling asleep.
- Anxiety.
- Irritability.

- Restlessness.
- Sneezing.
- Irritated eyes, red eyes.
- Dryness of the mouth and throat.
- Nausea.
- Flushing.

Frequency not known:

- Blurred vision.
- Drowsiness.
- Dizziness or light-headedness, seeing or hearing things that are not there.
- High blood pressure.
- Weakness.
- Confusion.
- Fear.
- Pain.
- Low blood pressure.
- Increased nasal discharge.
- Vomiting.
- Reduced appetite.
- Thirst.
- Increased sweating.
- Unusual paleness.
- Goose bumps (piloerection).
- Difficult or painful urination.
- Retention of urine.
- Local stinging or burning of the nose, stuffy nose, dry nose.

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- Worsening of nasal congestion (rebound congestion), causing a blocked or runny nose, sneezing or itchy nasal passages.
- Increased saliva flow.
- Cold extremities.
- Fainting.
- Loss of appetite.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SINAREST.

5. How to store SINAREST:

- Store at or below 25 °C.
- Do not remove from outer carton until required for use.
- Keep container tightly closed when not in use.
- The product should be discarded if the solution becomes discoloured.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What SINAREST contains

The active ingredient is oxymetazoline hydrochloride.

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.

The other ingredients are: Benzalkonium chloride (preservative), disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium hydroxide, purified water.

What SINAREST looks like and contents of the pack

Colourless, clear solution.

White plastic bottle (HDPE) or amber glass bottle 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.

Holder of certificate of registration

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SINAREST 0,025 %: 44/16.1/0745

SINAREST 0,05 %: 44/16.1/0746

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5 June 2014

Access to the corresponding Professional Information

The full Professional Information leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.

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