

Patient Information Leaflet

Vicks Sinex Micromist 0.05% w/v Nasal Spray Solution oxymetazoline hydrochloride

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

This medicine is available without prescription. However, you still need to use Vicks Sinex Micromist carefully to get the best results from it.

- **Keep this leaflet.** You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your pharmacist if your symptoms worsen or do not improve after 7 days.
- If any of the side effects gets serious or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What Vicks Sinex Micromist is and what it is used for

Vicks Sinex Micromist is a nasal spray used for localised relief of the symptoms of a blocked nose in association with a cold, hay fever or sinusitis (inflammation of the passages leading to the nose). The effect of the spray starts after several minutes and lasts for 6-8 hours. The active substance is oxymetazoline hydrochloride.

2. Before you use Vicks Sinex Micromist

Do not use Vicks Sinex Micromist if you:

- are allergic (hypersensitive) to the active substance oxymetazoline hydrochloride or any of the other ingredients of Vicks Sinex Micromist (see section 6)
- have inflamed skin or mucous membranes of your nostrils or have scabs in your nose.

Do not give Vicks Sinex Micromist to children under 12 years of age

Take special care with Vicks Sinex Micromist

Before using tell your doctor if you have:

- difficulty urinating due to an enlarged prostate gland
- high blood pressure
- heart disease including angina
- diabetes
- disturbance in your thyroid function
- hepatic or renal disorder
- suffer from increased eyeball-pressure (narrow-angle glaucoma)

Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those obtained without a prescription.

- **monoamine oxidase inhibitors (MAOIs)** are used in the treatment of Parkinson's disease and depression - **Do not use** Vicks Sinex Micromist if you have taken MAOIs during the last two weeks
- **phenothiazines and tricyclic antidepressants** – inform your doctor if you are taking drugs used in the treatment of depression such as amitriptyline and imipramine
- **high blood pressure medicines** - inform your doctor before use if you are taking digoxin, beta blockers or any other drugs for lowering blood pressure
- **Parkinson's disease medicine (such as bromocriptine)** - treatment with Vicks Sinex Micromist may be affected if it is used at the same time.
- **Do not take** with other medications containing decongestants

Pregnancy and breast-feeding

Vicks Sinex Micromist should be avoided during pregnancy or if breast feeding, unless otherwise advised by your doctor.

Driving and using machines

No effect on ability to drive or use of machinery has been observed.

Important information about some of the ingredients of Vicks Sinex Micromist

This medicine contains 0.01 mg **benzalkonium chloride** in each dose (1 spray) which is equivalent to 0.2 mg/ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

This medicine contains 0.1 mg **benzyl alcohol** in each dose (1 spray) which is equivalent to 2 mg/ml. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

3. How to use Vicks Sinex Micromist

Always use Vicks Sinex Micromist exactly as your pharmacist or doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Vicks Sinex Micromist is for use in your nose only.

Dosage: The recommended dose is

Adults and Children over 12 years: 1 or 2 sprays per nostril every 6 to 8 hours unless advised otherwise by your doctor.

Children under 12 years: Do not use

Do not exceed the recommended dose

Do not use for more than 7 days in a row.

If used over a longer period Vicks Sinex Micromist may cause a blocked nose.

Contact your doctor if symptoms worsen or do not improve after 7 days.

Administration:

1. Remove the cap. Keep the bottle upright with the nasal applicator just into the nostril. Hold the other nostril closed.
2. Spray and breathe in deeply through your nose at the same time. Repeat for the other nostril.
3. Wipe the nasal applicator with a clean, wet tissue and replace the cap immediately after application.

If you use more Vicks Sinex Micromist than you should

If you use too much Vicks Sinex Micromist you should contact your doctor or go to a hospital immediately and take the bottle or pack with you.

If you forget to use Vicks Sinex Micromist

Do not take a double dose if you forget to take the previous dose; instead, continue using according to the administration instructions

If you get Vicks Sinex Micromist in your eyes

Rinse thoroughly with water. Seek medical attention if eye irritation persists
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vicks Sinex Micromist can cause side effects, although not everybody gets them.

• **Rare (<1/1000):**

Eye disorders: Eye irritation, discomfort or redness

Respiratory: Discomfort or irritation in the nose, mouth or throat, sneezing

• **Very rare (<1/10,000):**

Cardiovascular: Tachycardia, palpitations, increased blood pressure

CNS: Insomnia, nervousness, tremor, anxiety, restlessness, irritability, headache

Gastrointestinal: Nausea

Do not use for more than 7 days in a row. If used over a longer period Vicks Sinex Micromist may cause a blocked nose.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vicks Sinex Micromist

Keep out of the sight and reach of children

Do not store above 25°C.

Do not use Vicks Sinex Micromist after the expiry date which is printed on the carton. The expiry date refers to the last day of the month stated.

Use this medicine within 12 months of first opening of the bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help protect the environment.

6. Further information

What Vicks Sinex Micromist contains

The active substance is: oxymetazoline hydrochloride 0.5 mg/ml

The other ingredients are: levomenthol, sodium citrate dihydrate, polysorbate 80, citric acid anhydrous, benzyl alcohol, benzalkonium chloride solution, camphor, disodium edetate dihydrate, cineole, sorbitol 70% and purified water

What Vicks Sinex Micromist looks like and contents of the pack

Vicks Sinex Micromist is a metered dose nasal pump spray. The pack contains an amber glass bottle with a white pump on top. The bottle is filled with 15 ml of product. The solution is clear to slightly yellowish in colour. Each bottle contains a minimum of 265 sprays.

Marketing Authorisation Holder:

WICK Pharma, Zweigniederlassung der Procter & Gamble GmbH, 65823 Schwalbach, Germany
(send all enquiries to this address).

Manufacturer:

Procter & Gamble Manufacturing GmbH, Procter & Gamble Strasse 1, 64521 Gross-Gerau, Germany

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