

Vicks Sinex Micromist

Oxymetazoline hydrochloride 0.05% w/v

Patient Information Leaflet

In this leaflet:

1. What Vicks Sinex Micromist is and what it is used for
2. Before you use Vicks Sinex Micromist
3. How to use Vicks Sinex Micromist
4. Possible side effects
5. How to store Vicks Sinex Micromist
6. Further information

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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact your pharmacist if your symptoms worsen or do not improve after 7 days.

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 within 2-30 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)
- are taking (or have taken during the last 14 days) monoamine oxidase inhibitors (MAO inhibitors are used in the treatment of Parkinson's disease and depression)
- have had an operation to remove your pituitary gland
- have inflamed skin or mucous membranes of your nostrils or have scabs in your nose
- do not take with other medications containing decongestants
- have had nasal surgery
- suffer from a tumour of the adrenal glands

➤ **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:

- high blood pressure
- heart disease including angina
- diabetes
- disturbance in your thyroid function
- an enlarged prostate gland

- hepatic or renal disorder
 - occlusive vascular disease
 - suffer from increased eyeball-pressure (narrow-angle glaucoma)
- If any of the following occur, Vicks Sinex Micromist should be stopped;**

- hallucinations
- restlessness
- sleep disturbances

Keep away from eyes

➤ **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 14 days
- **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 bethanidine, debrisoquine and guanethidine as their effect may be reduced
- **beta blockers** - inform your doctor before use if you are taking these, as their effect may be reduced
- **Parkinson's disease medicine (bromocriptine)** – treatment with Vicks Sinex Micromist may be affected if it is used at the same time
- **appetite suppressants and amphetamine-like psychostimulants** – inform your doctor before use if you are taking drugs for obesity
- **cardiac glycosides** – inform your doctor before use as it can cause irregular heart beat (dysrhythmias) if it is taken at the same time
- **ergot alkaloids** (ergotamine and methysergide) – inform your doctor before use if you are taking these treatments for migraines as they can cause increased side effects

➤ **Pregnancy and breastfeeding**

Ask your doctor or pharmacist for advice before using Vicks Sinex Micromist. The spray should be used with caution during pregnancy or if breastfeeding.

➤ **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 0.2mg/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 or more than the recommended dose, 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 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** (occurring in less than 1 in 1,000):
Eye: Eye irritation, dryness, discomfort or redness
Respiratory: Discomfort or irritation in the nose, mouth or throat; Sneezing
- **Very rare** (occurring in less than 1 in 10,000):
Cardiovascular: Tachycardia (rapid heartbeat), palpitations, increased blood pressure
CNS: Insomnia (difficulty in sleeping), nervousness, tremor, anxiety, restlessness, irritability, headache
Gastrointestinal: Nausea
- Prolonged and/or heavy use beyond the recommended use of 7 days, may in rare instances lead to cardiovascular and/or CNS effects.

➤ **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 reach and sight 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. One spray gives 25µg of oxymetazoline hydrochloride.

The other ingredients are: levomenthol, sorbitol, sodium citrate dihydrate, polysorbate 80, citric acid anhydrous, benzyl alcohol, benzalkonium chloride solution, camphor, disodium edetate dihydrate, eucalyptol 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. Each bottle contains a minimum of 265 sprays.

Marketing Authorisation Holder:

Procter & Gamble (Health & Beauty Care) Limited, The Heights, Brooklands, Weybridge, Surrey, KT13 0XP, UK (send all enquiries to this address).

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

PL 00129/0133

Text Revision: 03/2022