

Vicks Sinex Soother 0.5 mg/ml Nasal Spray, Solution

Oxymetazoline hydrochloride

Package leaflet: Information for the user

What is in this leaflet:

1. What Vicks Sinex Soother is and what it is used for
2. What you need to know before you use Vicks Sinex Soother
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Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

This medicine is available without prescription. However, you still need to use Vicks Sinex Soother 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 talk to a doctor if you do not feel better or if you feel worse after 3 days.

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

Vicks Sinex Soother is a nasal spray used for localised relief of the symptoms of a blocked nose in association with a cold or rhinitis.

The effect of the spray starts after several minutes and lasts up to 12 hours.

2. What you need to know before you use Vicks Sinex Soother

Do not use Vicks Sinex Soother:

- if you are allergic (hypersensitive) to the active substance oxymetazoline hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you are taking (or have taken during the last 2 weeks) monoamine oxidase inhibitors (MAO inhibitors are used in the treatment of Parkinson's disease and depression)
- if you suffer from acute heart disease or cardiac asthma
- if you suffer from increased eyeball-pressure (narrow-angle glaucoma)
- if you have had an operation to remove your pituitary gland
- if you have inflamed skin or mucous membranes of your nostrils or have scabs in your nose

➤ **Do not give this medicine to children under 12 years of age.**

➤ **Warnings and precautions**

Talk to your doctor or pharmacist before using Vicks Sinex Soother if you have:

- high blood pressure
- heart disease, including angina
- diabetes
- thyroid problems

- enlarged prostate gland (prostatic hypertrophy)
- **Other medicines and Vicks Sinex Soother**
Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines
 - **monoamine oxidase inhibitors** (MAOIs) are used in the treatment of Parkinson's disease and depression). **Do not use** Vicks Sinex Soother if you have taken MAOIs during the last two weeks.
 - **tricyclic antidepressants** – inform your doctor if you are taking drugs used in the treatment of depression such as amitriptyline and imipramine.
 - **Beta blockers or high blood pressure medicines** - inform your doctor before use if you are taking any of these.
 - **Parkinson's disease medicine (bromocriptine)** - inform your doctor before use if you are taking this medicine.
- **Pregnancy and Breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
The spray should be used with caution during pregnancy or if breast feeding.
- **Driving and using machines**
Vicks Sinex Soother has no influence on the ability to drive or use machines.
- **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 Soother

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

- **The recommended dose is:**
Adults and children over 12 years: 1-2 sprays in each nostril no more than 2-3 times daily.
Children under 12 years – Do not use.
Do not exceed the recommended dose.
Do not use for longer than 5-7 days in a row. If used over a longer period, Vicks Sinex Soother may cause a blocked nose.
Contact your doctor if symptoms worsen or do not improve after 3 days.
- **Method of 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. Adults and children over 12 years may repeat steps 1 and 2 once if necessary.
 4. Wipe the nasal applicator with a clean, wet tissue and replace the cap immediately after application.

- **If you use more Vicks Sinex Soother than you should**
If you use too much Vicks Sinex Soother and you experience any unwanted effects or symptoms, seek medical advice immediately and take the bottle or pack with you.
- **If you forget to use Vicks Sinex Soother**
Do not take a double dose to make up for a forgotten dose; instead, continue using according to the administration instructions.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- **Uncommon** (may affect up to 1 in 100 people):
Sneezing, dryness or irritation in the nose, mouth or throat.
- **Rare** (may affect up to 1 in 1000 people):
Anxiety, fatigue, irritability, disturbed sleep in children, rapid heartbeat, palpitations, raised blood pressure, blocked nose, swelling of the nasal lining, headache, nausea, flushing, rash and visual disturbances.
- **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 website at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vicks Sinex Soother

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and label of the bottle after EXP. The expiry date refers to the last day of that month.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Vicks Sinex Soother contains

The **active substance** is: oxymetazoline hydrochloride 0.5 mg/ml. One spray (equivalent to 0.05 ml) contains approximately 25 micrograms oxymetazoline hydrochloride.

The **other ingredients** are: sorbitol, sodium citrate, polysorbate 80, benzyl alcohol, citric acid anhydrous, benzalkonium chloride solution, acesulfame potassium, levomenthol, cineole, disodium edetate, aloe dry extract, levocarbonyl, water, purified. (See section 2 Vicks Sinex Soother contains Benzalkonium chloride).

What Vicks Sinex Soother looks like and contents of the pack

Vicks Sinex Soother nasal spray solution 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.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Procter & Gamble(Health & Beauty Care) Limited, Weybridge, Surrey KT13 0XP United Kingdom

Manufacturer:

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

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