



Vicks Sinex Soother 0,5 mg/ml nasal spray Oxymetazoline Hydrochloride

Patient information leaflet

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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 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.
- You should contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 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 Vicks Sinex Soother (see section 6)
- 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)
- suffer from acute heart disease or cardiac asthma
- suffer from increased eyeball-pressure (narrow-angle glaucoma)

- have had an operation to remove your pituitary gland
- have inflamed skin or mucous membranes of your nostrils or have scabs in your nose.

⚠ Vicks Sinex Soother is not recommended for children under 12 years of age

⚠ Take special care with Vicks Sinex Soother

Before using tell your doctor if you have:

- high blood pressure,
- heart disease,
- diabetes,
- disturbance in your thyroid function.

⚠ 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 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

- **high blood pressure medicines** – inform your doctor before use if you are taking bethanidine, debrisoquine and guanethidine as their effect may be reduced
- **Parkinson's disease medicine (bromocriptine)** – treatment with Vicks Sinex Soother may be affected if it is used at the same time.

⚠ Pregnancy and Breast-feeding

Ask your doctor or pharmacist for advice before using Vicks Sinex Soother.

The spray should be used with caution during pregnancy or if breast-feeding.

⚠ Driving and using machines

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

⚠ Important information about some of the ingredients of Vicks Sinex Soother

Benzalkonium chloride (a preservative) is an ingredient in Vicks Sinex Soother which might cause swelling of nasal mucosa, especially during long-term use.

3. How to use Vicks Sinex Soother

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

⚠ Dosage: 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 - not recommended

Do not exceed the recommended dose.

Do not use for longer than 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.

This medicine may be prescribed by your doctor for other conditions and/or at other doses, in this case always follow your doctor's instructions.

⚠ 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 10 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 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 Soother

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 pharmacist.

4. Possible side effects

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

- **Uncommon** (occurring in less than 1 in 100 people): Sneezing, dryness or irritation in the nose, mouth or throat.
- **Rare** (occurring in less than 1 in 1,000 people): Anxiety, fatigue, irritability, disturbed sleep in children, rapid heart beat, palpitations, raised blood pressure, blocked nose, swelling of the nasal lining, headache, nausea, flushing, rash and visual disturbances.

⚠ If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vicks Sinex Soother

Keep out of the reach and sight of children. Store below 25°C.

Do not use Vicks Sinex Soother after the expiry date which is printed on the carton. The expiry

date refers to the last day of the month stated.

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 to protect the environment.

6. Further information

What Vicks Sinex Soother contains

The **active substance** is: Oxymetazoline hydrochloride 0.5 mg/ml.

The **other ingredients** are: sorbitol, sodium citrate dihydrate, tyloxapol, chlorhexidine digluconate solution, citric acid anhydrous, aloe dry extract, benzalkonium chloride solution, acesulfame potassium, menthol (levo), cineole, disodium edetate (dihydrate), carvone (levo), sodium hydroxide, purified water. (See end of section 2 for benzalkonium chloride).

What Vicks Sinex Soother looks like and contents of the pack

Vicks Sinex Soother 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 10 ml or 15 ml of product.

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

This medicinal product is authorised in the Member States of the EA under the following names:

Sweden: Vicks Sinex, 0,5 mg/ml, nässpray, lösnings
Austria: WICK SinexAloe Nasenspray. **Belgium:** Vicks SinexAloe
Germany: WICK Sinex avara Nasenspray
The Netherlands: Vicks Sinex Aloe. **Portugal:** Sinexsensi
Spain: Sinexsensi. **UK:** Vicks Sinex Soother
This leaflet was last approved in 09/2009.

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