

# SUDAFED<sup>®</sup>

## SINUS-EASE

### 0.1% Nasal Spray Xylometazoline hydrochloride

- This medicine is used to help clear the blocked up feeling in your nose and sinuses, and helps relieve congestion caused by sinusitis, colds and hayfever.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
  - There are some people who should not take this medicine. *To find out if you are one of them see section 2* ▶
  - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in section 2. *See section 2* ▶
- **Follow the dosage instructions carefully.**  
These are shown in the table. *See section 3* ▶

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

## 1 What the medicine is for

Sudafed Sinus-Ease 0.1% Nasal Spray is a medicine which is used to help clear the blocked up feeling in your nose and sinuses, and helps relieve congestion caused by sinusitis, colds and hayfever. The metered spray gives an exact dose that lasts for up to 10 hours. The spray contains xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion. This medicine is for use in adults and children aged

12 years and over.

## 2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### ⚠ Do not use this medicine...

- If you have ever had a **bad reaction** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you have recently had **neurosurgery**.
- If you have had your **pituitary gland** removed.
- For a child under 12 years old

If any of these apply to you, **get advice from a doctor or pharmacist without taking Sudafed Sinus-Ease 0.1% Nasal Spray.**

### ⚠ Talk to your doctor or pharmacist...

- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**.
- If you have an **overactive thyroid gland**.
- If you suffer from a **heart disease** (e.g. **long QT syndrome**)

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

### ⚠ If you are pregnant or 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 taking this medicine.

### ⚠ Some of the ingredients can cause problems

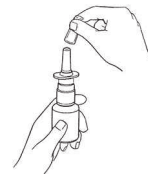
- The medicine contains 1.96 mg benzalkonium chloride in each bottle of 10 ml, and

2.94 mg benzalkonium chloride in each bottle of 15 ml, which is equivalent to 0.196 mg/ml of product. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

## 3 How to use this medicine

Follow the instructions and study the pictures below to ensure that you use Sudafed Sinus-Ease 0.1% Nasal Spray correctly:

- **Step 1.** Remove the plastic cap from the nozzle.



- **Step 2.** When using the spray for the first time, press the plunger downwards while supporting the base with your thumb as shown in the diagram and release until a single spray is delivered.



- **Step 3.** Hold the bottle upright and place the nozzle into one nostril. Press the plunger downwards and at the same time breathe in through your nose. Release the plunger and remove the nozzle from the nostril. Repeat this process for the other nostril.



turn over ▶

- **Step 4.** Wipe the nozzle and replace the plastic cap after use.



### Check the table that follows to see how much medicine to use.

- Do not use more than the stated dose shown in the table.

#### **i** Children under 12 years

Do not give to children under 12 years old.

#### **i** Adults and Children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	One spray into each nostril 2 to 3 times a day over
<ul style="list-style-type: none"> <li>■ Do not take more than 3 doses in 24 hours.</li> <li>■ Do not use continuously for more than 7 days.</li> <li>■ If symptoms persist or worsen, talk to your doctor or pharmacist.</li> </ul>	

#### **!** If anyone has too much

If anyone has too much contact a doctor or your nearest Accident & Emergency Department (Casualty) taking this leaflet and pack with you.

#### **!** If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that you do not take more than 3 doses in 24 hours. **Do not** take a double dose.

## 4 Possible side-effects

Like all medicines, Sudafed Sinus-Ease 0.1% Nasal Spray can have side-effects, although not everybody gets them.

- Uncommon - Nosebleeds
- Occasionally people may experience local irritation such as burning, soreness, dryness, stinging, itching or sneezing.
- Nausea and headache may rarely occur.
- If this medicine is used continuously for long periods, congestion symptoms may return.

### 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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Storing this medicine

Do not store above 25°C.

Use within 20 weeks of opening the bottle.

Keep the product out of the sight and reach of children.

Do not use your medicine after the end of the month shown as an expiry date on the packaging.

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's in this medicine?

**The active ingredient in Sudafed Sinus-Ease 0.1% Nasal Spray is:** Xylometazoline hydrochloride 0.1% w/v.

**Other ingredients are:** Benzalkonium chloride, disodium edetate, sodium dihydrogen phosphate, sodium monohydrogen phosphate, sodium chloride, sorbitol solution, purified water.

### What the medicine looks like

Sudafed Sinus-Ease 0.1% Nasal Spray is a clear colourless solution in a 10 ml or 15 ml bottle.

**Marketing Authorisation holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

**Manufacturer:** Delpharm Orléans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

**This leaflet was last revised in January 2023.**

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