

# SUDAFED<sup>®</sup>

## 0.1% w/v NASAL SPRAY SOLUTION

Xylometazoline hydrochloride

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 Sudafed Nasal Spray 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 any of the side-effects get serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

- What Sudafed Nasal Spray is and what it is used for
- Before you take Sudafed Nasal Spray
- How to take Sudafed Nasal Spray
- Possible side-effects of Sudafed Nasal Spray
- How to store Sudafed Nasal Spray
- Contents of the pack and other information

## 1 What Sudafed Nasal Spray is and what it is used for

Sudafed Nasal Spray is a medicine which is used to help clear the stuffy, blocked up feeling in your nose and sinuses caused by colds and allergies such as hay fever.

The spray contains xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion.

This product is non-drowsy.

This medicine is for use in adults and children aged 6 years and over.

## 2 What you need to know before you use Sudafed Nasal Spray

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.

### **X** Do not take Sudafed Nasal Spray...

- If you have ever had a hypersensitive reaction (e.g. rash, swelling of the face and throat, difficulty breathing) to xylometazoline or to any of the ingredients listed in Section 6.
- 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 brain surgery via the nose or mouth.
- If you are **pregnant** or breast-feeding.
- Children under 6 years.

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

### **!** Warnings and Precautions. Before using Sudafed 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**.
- Before use in children aged 6 - 12 years.

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

**Special Warning:** If this medicine is used continuously for long periods, congestion symptoms may return.

### **!** Pregnancy and Breast-feeding

- Do not use this medicine if you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **!** Other Medicines and Sudafed Nasal Spray

- Please tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **!** Driving and Using Machines

- Sudafed Nasal Spray has no or negligible influence on the ability to drive and use machines.

### **!** Some of the ingredients can cause problems

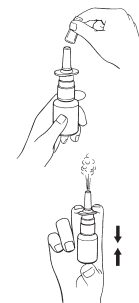
- Benzalkonium chloride is an irritant which may cause skin reactions.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as the product may be swallowed.

## 3 How to use Sudafed Nasal Spray

Follow the instructions and study the pictures below to ensure that you use Sudafed Nasal Spray correctly:

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



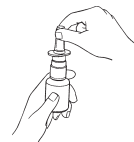
- **Step 2.** When using the spray for the first time, press the plunger downwards while supporting the base with your thumb as shown in the diagram and release until a single spray is delivered.

turn over ►

- **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.



- **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 6 years**

This medicine is not recommended for children under 6 years.

### **i Children 6 - 12 years of age**

Age	Dose
<b>Children 6 - 12 years of age</b>	<b>One spray</b> into each nostril 2 or 3 times a day

- Do not take more than 3 doses in 24 hours.
- **Children aged 6 - 12 years:**  
Use only when simple measures have failed to provide adequate relief. Do not exceed the maximum daily dose: 3 doses in each nostril. Do not use with other cough and cold medicines. Do not use continuously for more than 5 days.
- No dose adjustment is required for patients with kidney or liver problems.

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

Age	Dose
<b>Adults and children 12 years and over</b>	<b>One spray</b> into each nostril 2 or 3 times a day

- Do not take more than 3 doses in 24 hours.
- **Adults and children over 12 years:**  
Do not use continuously for more than 7 days.
- If symptoms persist talk to your doctor.
- No dose adjustment is required for the elderly or patients with kidney or liver problems.

### **! If you use more Sudafed Nasal Spray than you should**

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

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

If you forget to take use Sudafed Nasal Spray, 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**

Sudafed Nasal Spray can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

## **5 Storing this medicine**

Do not store above 25°C.

Keep the container in the outer carton.

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

Do not use your medicine after the end of the month shown as an expiry date on the carton and label after EXP. The expiry date refers to the last day of that month.

## **6 Contents of the pack and other information**

### **What's in this medicine?**

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

Each metered spray (0.14 ml) delivers 140 micrograms of xylometazoline hydrochloride.

**Other ingredients are:** Benzalkonium chloride solution, Disodium edetate, Sodium dihydrogen phosphate dihydrate, Disodium phosphate dihydrate, Sodium chloride, Sorbitol, Liquid (Non-crystallising), Purified water.

### **What Sudafed Nasal Spray looks like**

Sudafed Nasal Spray is a clear colourless solution in a 15 ml bottle.

Each bottle contains an average of 53 doses.

**Product Authorisation holder:** McNeil Healthcare (Ireland) Ltd. Airtown Road, Tallaght, Dublin 24, Ireland.

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






**This leaflet was revised July 2013.**

Sudafed is a registered trade mark.

**McNeil**  
Healthcare (Ireland) Ltd.

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13-0016



<b>SUDAFED Nasal Spray 15 ml</b>			<b>IE</b>	
Component Number	Flat Leaflet	Dimensions	NOTP002	Version
F309501		148 x 210 mm		V9.1
Safety code		Job Bag Number		
Lætus n° 32		13-0016		
FRONT		REAR		
Colours				
 NOIR	 NOIR			
 PMS 300	 PMS 300			
				

AFFILIATE APPROVAL

Approved by / Approuvé par :

Name: .....

Date: ...../...../.....

Signature: \_\_\_\_\_

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