

# SUDAFED®

## PLUS

### BLOCKED NOSE

1 mg/50 mg/ml

### Nasal Spray Solution

Xylometazoline hydrochloride & Dexpanthenol

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 pharmacist or doctor has told you.

- 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 pharmacist or doctor. 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 after 7 days

In the rest of this leaflet, Sudafed Plus Blocked Nose 1 mg/50 mg/ml Nasal Spray solution will be called Sudafed Plus.

#### What is in this leaflet

1. What Sudafed Plus is and what it is used for
2. Before you use Sudafed Plus
3. How to use Sudafed Plus
4. Possible side effects
5. How to store Sudafed Plus
6. Contents of the pack and other information

## 1. What Sudafed Plus is and what it is used for

Sudafed Plus 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 allergies (such as hay fever). The spray contains:

- xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion, and
- dexpanthenol which is a derivative of the vitamin pantothenic acid, which promotes healing and protects the mucous membrane (lining) of the nose.

This medicine is for use in adults and children aged 12 years and over.

## 2. Before you use Sudafed Plus

This medicine is for short term use only.

### **X** 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 any other decongestant medicines, including other xylometazoline products
- if you have recently taken any other medicine containing any decongestant, including those with xylometazoline. This includes decongestant tablets, syrups and other nose sprays
- if you have high blood pressure or heart disease
- if you have an adrenal marrow tumour (*phaeochromocytoma*)
- if you have diabetes
- if you have an overactive thyroid gland
- if you have closed angle glaucoma
- if you are taking drugs to slow down the heart rate known as beta blockers
- if you have a condition that causes the inside of the nose to become dry and irritated (*rhinitis sicca*) or any other long standing inflammation inside the nose
- 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 (*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 pharmacist or doctor without using Sudafed Plus.**

### Do not take with other decongestants

While using Sudafed Plus, do not use any other decongestants, including anything containing xylometazoline. **Do not use if you have recently taken any other medicine containing any decongestant**, including those with xylometazoline. This includes decongestant tablets, syrups and other nose sprays.

### **A** Warnings and precautions

Talk to your pharmacist or doctor before using Sudafed Plus:

- if you have elevated pressure inside the eye (*glaucoma*)
- if you have long-term inflammation of the lining of the nose (*chronic rhinitis*)
- if you have a metabolic disorder called *porphyria*
- if you have an enlarged prostate.
- if you have inadequate blood flow to the heart due to narrowing of the arteries (*occlusive vascular disease*).
- if you have a rare heart condition that causes heart rhythm problems called *long QT syndrome*

Stop using Sudafed Plus if any of the following occur after using it:

- hallucinations (if you hear, see, smell, taste or feel things that seem real but are not)
- restlessness
- sleep disturbances.

Using the spray wrongly, or using too much, can cause side effects (see section 4, Possible side effects).

Using the spray for too long or more often than recommended can cause rebound nasal congestion even after stopping treatment (see section 4, Possible side effects).

Keep away from the eyes.

### Other medicines and Sudafed Plus

Do not use if you are taking or have recently taken:

- any other medicine containing any decongestant, including those with xylometazoline. This includes decongestant tablets, syrups and other nose sprays.

Tell your pharmacist or doctor before using this nose spray if you are taking:

- medicines for nasal congestion, including tablets, syrups or other nose sprays
- medicines for high or low blood pressure
- medicines for depression, specifically the antidepressants called
  - tricyclic antidepressants e.g. amitriptyline
  - monoamine oxidase inhibitors (MAOIs) e.g. moclobemide or have taken these medicines in the last two weeks
- medicines for heart failure and irregular heartbeats (digoxin and other cardiac glycosides)
- medicines for migraine (specifically ergotamine and methysergide)
- medicines to suppress appetite and treat ADHD (amphetamine-like stimulants such as phentermine, dexamphetamine and lisdexamfetamine).

**Tell your pharmacist or doctor** if you are taking, have recently taken or might take any other medicines.

### If you are pregnant or breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be used during pregnancy due to a lack of safety data in pregnant women. This medicine should not be used during breastfeeding since it is not known whether xylometazoline hydrochloride passes into breast milk.

### Driving and using machines

This medicine is not expected to affect your ability to drive or use machines.



### 3. How to use Sudafed Plus

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

**The recommended dose** for adults and children 12 years and over is **one spray into each nostril up to 3 times a day as necessary**. The maximum daily dose is 3 doses in 24 hours.

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

**Do not use more than the stated dose.**

**Do not use this medicine for more than 7 days.**

If you do not feel better after 7 days of treatment, talk to a doctor.

After first opening, use the product within 3 months.

**If the bottle gets dropped with the cap off**, check that the spray still squirts straight upwards when the bottle is held upright (see picture 1). If not, throw it away. If the spray is still working correctly, clean the nozzle thoroughly with an antiseptic wipe.

#### Method of administration

Sudafed Plus is intended for use in the nose. Follow the instructions and study the pictures below to ensure that you use Sudafed Plus correctly:

**First remove the protective cap from the sprayer.**

Before the first use, press the spray head 5 times away from the face, until a fine spray appears. If the spray has not been used for a long time the head should be pressed twice before use, away from the face.

**Insert the sprayer tip as upright as possible into one nostril** and press the spray head once (picture 2). Gently inhale through the nose while spraying. If necessary, repeat this for the other nostril (up to 3 times a day as needed). After each use, wipe the sprayer tip with a paper tissue and place the protective cap back on the bottle.

**Do not share.** For hygiene reasons and to avoid infections, each spray bottle **should only be used by one person**.

#### If you use more medicine than you should

If you use more of this medicine than you should or if you accidentally take in too much of it, contact your doctor or your nearest emergency department. Take this leaflet and pack with you.

The following side effects might occur:

- constricted or dilated eye pupils
- fever, sweating, decreased body temperature
- pale skin, blue skin or lips
- nausea
- drowsiness, convulsions, loss of consciousness
- fast or slow heart rate, changes to heart rhythm, circulatory failure, cardiac arrest
- high or low blood pressure
- breathing problems
- anxiety, agitation, hallucinations.

If you notice any of these symptoms, **seek medical help immediately**.



#### If you forget to use the medicine

If you forget to use a dose, use the next dose when needed, but do not use more than 3 doses in 24 hours. Do not use a double dose to make up for a forgotten dose.

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):

- hypersensitivity reaction such as swelling of the skin and mucous membranes, skin rash, itching

**Rare** (may affect up to 1 in 1,000 people):

- palpitations (feeling your heartbeat), faster heartbeat, high blood pressure.

**Very rare** (may affect up to 1 in 10,000 people):

- nosebleeds.
- restlessness, difficulty in sleeping
- fatigue (drowsiness, sedation), headache
- hallucinations (you hear, see, smell, taste or feel things that seem real but are not)
- false belief of being under threat (*paranoid delusions*)
- heart rhythm disorders
- rebound nasal congestion (*rhinitis medicamentosa*), causing irritation and inflammation of the nose (especially after the spray is used frequently and/or for many days)
- seizures.

**Frequency not known** (cannot be estimated from the available data):

- burning, irritation and dryness of the lining of the nose, sneezing
- irritability, anxiety and excitability.
- feeling sick (nausea)
- reduced response to the spray especially after using it frequently and/or for many days

#### 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](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. How to store Sudafed Plus

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

After first opening of the container, **the product should be used within 3 months**.

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

Do not store above 25°C.

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 protect the environment.

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

#### What Sudafed Plus contains

- The active substances are xylometazoline hydrochloride and dexamethasone.  
Each 1 ml of nasal spray contains 1 mg xylometazoline hydrochloride and 50 mg dexamethasone.  
One spray contains 0.1 ml of nasal spray, containing 0.1 mg xylometazoline hydrochloride and 5.0 mg dexamethasone.
- The other ingredients are potassium dihydrogen phosphate, disodium phosphate dodecahydrate and water for injections.

#### What Sudafed Plus looks like and contents of the pack

Sudafed Plus is a clear, colourless to slightly yellowish solution available in a 10 ml HDPE bottle with spray pump. The 10 ml of nasal spray solution is sufficient for 80 sprays.

#### Marketing Authorisation Holder

McNeil Products Limited, High Wycombe, Buckinghamshire, HP12 4EG, UK.

#### Manufacturer

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