

SUDAFED[®]

PLUS

BLOCKED NOSE



1mg/50mg/ml

Nasal Spray Solution

Xylometazoline hydrochloride & Dexamethasone

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 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 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 after 7 days

In the rest of this leaflet, Sudafed Plus Blocked Nose 1mg/50mg/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 Blocked Nose 1mg/50mg/ml Nasal Spray solution 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
- dexamethasone 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 have a dry inflammation of the lining of the nose with formation of crusts (*rhinitis sicca*).
- if you have had your pituitary gland removed.
- if you have recently had brain surgery (*neurosurgery*).
- if you are taking, or have taken in the last two weeks, drugs for depression known as monoamine oxidase inhibitors (MAOIs).
- for a child under 12 years old.

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

! Warnings and precautions

Talk to your doctor or pharmacist before taking Sudafed Plus:

- if you have high blood pressure or heart disease (e.g., long QT syndrome).
- if you have elevated pressure inside the eye (*glaucoma*), particularly if you suffer from narrow-angle glaucoma.
- if you have chronic rhinitis,
- if you have an overactive thyroid gland.
- if you have diabetes
- if you have adrenal marrow tumour (*pheochromocytoma*),
- if you have a metabolic disorder called porphyria,
- if you have an enlarged prostate.

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 at too high a dose may cause swelling and possibly damage the lining of the nose.

Avoid direct contact of this medicine with the eyes.

Other medicines and Sudafed Plus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are taking any of the following:

- Medicines to treat nasal congestion such as pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline
- Medicines to reduce blood pressure (e.g. methyl dopa)
- Medicines which increase blood pressure (e.g. doxapram, ergotamin, oxytocin, monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants).

Consult a doctor before using Sudafed Plus if you use any of these medicines.

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.

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 breast-feeding 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 doctor or pharmacist has told you. Check with your doctor or pharmacist 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 ingest large quantities of the medicine, contact your doctor or your nearest emergency department. Take this leaflet and pack with you. The following side effects might occur: constriction of the eye pupils (meiosis), expansion of the eye pupils (mydriasis), fever, sweating, paleness of the skin, blue coloration of the skin or lips (cyanosis), nausea, convulsions, cardiac and vascular disorders (increased heart rate, slow heart rate, heart rhythm disorders, circulatory failure, cardiac arrest, high blood pressure (hypertension), respiratory disorders (swelling of the lungs, breathing problems), mental disorders (anxiety, agitation, hallucinations), you may also experience drowsiness, decreased body temperature, heart rate decelerations, and decrease in blood pressure, respiratory arrest and coma. If you notice any of these symptoms, contact your doctor 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
- nosebleeds

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

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

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

- restlessness, difficulty in sleeping, fatigue (drowsiness, sedation), headache, hallucinations
- heart rhythm disorders (arrhythmias)
- swelling of the lining of the nose (after discontinuation of the treatment)
- seizures (convulsion)

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

- burning and dryness of the lining of the nose, sneezing

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 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 dexpanthenol.
Each 1 ml of nasal spray contains 1 mg xylometazoline hydrochloride and 50 mg dexpanthenol.
One spray contains 0.1 ml of nasal spray, containing 0.1 mg xylometazoline hydrochloride and 5.0 mg dexpanthenol.
- 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

Famar Health Care Services Madrid, S.A.U., Avda. Leganes, 62, Alcorcon, 28923, Madrid.

or

Ursapharm Arzneimittel GmbH, Industriestrasse 35, 66129 Saarbrücken, Germany.

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