

Package leaflet: Information for the user

Sudafed Plus 1 mg/ml + 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 doctor or pharmacist have 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 or if you feel worse after 7 days (3 days in children).

What is in this leaflet

1. What Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is and what it is used for
2. What you need to know before you use Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution
3. How to use Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution
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1. What Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is and what it is used for

Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution contains xylometazoline hydrochloride and dexpanthenol. Xylometazoline hydrochloride rapidly constricts blood vessels in the nasal mucous membrane and reduces the swelling of the nasal mucous membrane. Dexpanthenol is a derivative of the vitamin pantothenic acid, which promotes healing and protects the nasal mucous membrane.

Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is used:

- for reducing the swelling of the nasal mucous membrane in nasal mucous membrane inflammation (rhinitis) and to promote healing of mucous membrane lesions,
- for relief in non-allergic nasal mucous membrane inflammation (vasomotor rhinitis),
- for the treatment of worsened breathing through the nose after nasal surgery; the use of Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution in this indication is possible only upon a doctor's recommendation.

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

2. What you need to know before you use Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

Do not use Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution:

- if you or your child are allergic to xylometazoline hydrochloride, dexpanthenol or any of the other ingredients of this medicine (listed in section 6),
- if you or your child have a dry inflammation of the nasal mucous membrane with formation of crusts (rhinitis sicca),
- if you or your child have had a surgical removal of the pituitary gland or other surgery exposing the meninges (lining of the brain).

This medicine must not be used in children under 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution:

- if you or your child are taking monoamine oxidase inhibitors (MAOIs) or other medicines that can raise blood pressure,
- if you or your child have elevated pressure inside the eye (glaucoma), particularly if you suffer from narrow-angle glaucoma,
- if you or your child have severe cardiovascular disease (e.g. long QT syndrome, coronary heart disease, high blood pressure),
- if you or your child have a metabolic disease (e.g. if you have diabetes, increased activity of the thyroid gland presenting with increased sweating, increased body temperature or increased heart rate),
- if you or your child have adrenal marrow tumour (pheochromocytoma),
- if you or your child have a metabolic disorder called porphyria,
- if you or your child have an enlarged prostate.

If any of the above apply to you, talk to your doctor or pharmacist before using Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

Long-term and incorrect use

This medicine should not be used continuously for more than 7 days (see section 3 below). Prolonged use or use of higher doses of this medicine may result in chronic swelling and possibly thinning (damage) of the nasal mucous membrane.

Use during chronic rhinitis may only be carried out under medical supervision owing to the danger of the thinning of the nasal mucosa.

Incorrect use or use of the excessive amounts of the spray can cause systemic undesirable effects, particularly in children (see section Possible side effects).

Avoid direct contact of this medicine with the eyes.

Children

Long-term usage and higher doses are to be avoided, especially in children.

Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is suitable for use only in children over 6 years of age. For children under

6 years of age, other medicinal products with lower doses of active substances are available.

You should supervise the use of this medicine in children under 12 years of age.

Other medicines and Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

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

Using Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution at the same time as some medicines for the treatment of depression (monoamine oxidase inhibitors of the tranylcypromine type or tricyclic antidepressants) as well as medicines which increase blood pressure may lead to an increase in blood pressure due to the cardiovascular effects of these substances.

Using Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution at the same time as some other medicines containing sympathomimetics (cough-and-cold medicines used to treat nasal congestion such as pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline, tuaminoheptane) may increase the undesirable effects on the cardiovascular and central nervous system.

Medicines to reduce blood pressure (e.g. methyldopa) should not be used together with xylometazoline due to its blood pressure increasing effect.

Consult a doctor before using Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution if you or your child use any of the above- mentioned medicines.

Pregnancy, breast-feeding and fertility

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 when used as recommended.

3. How to use Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

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 is one spray into each nostril up to 3 times a day as needed unless otherwise directed by your doctor. Do not use this medicine for more than 7 days. If you do not feel better or feel worse after 7 days of treatment, please consult the doctor. Next use is possible only after a break of several days.

If the child does not feel better or feels worse after 3 days of treatment, please consult the doctor.

Method of administration

Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is intended for nasal use.

First remove the protective cap from the sprayer.

Before the first use press the spray head 5 times until a fine spray appears. If the spray has not been used for 7 days or more, the head should be pressed twice before first re-use.



Insert the sprayer tip as upright as possible into one nostril and press the spray head once. Gently inhale through the nose while spraying. If necessary, repeat the procedure for the other nostril. After each use, wipe the sprayer tip with a paper tissue and place the protective cap back on the sprayer.



For hygienic reasons and to avoid infections, each spray bottle should only be used by the same person

Use in children

The recommended dose for children over 6 years of age is one spray into each nostril up to 3 times a day as needed. Regarding the duration of use in children, you should always consult a doctor.

If you use more Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution than you should

If you use more of this medicine than you should or if you accidentally ingest large quantities of the medicine, 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 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
- 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 Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

Do not use a double dose to make up for a forgotten dose. Continue administration as described in the dosage instruction.

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), 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 (primarily in children),
- heart rhythm disorders (arrhythmias),
- swelling of the nasal mucous membrane (after discontinuation of the treatment), nosebleed,
- seizures (convulsions; especially in children).

Not known (frequency cannot be estimated from the available data):

- burning and dryness of the nasal mucous membrane, 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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution

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

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

Do not store above 25°C

After first opening of the container, the product should be used within 6 months. Space is available on the carton after the phrase 'Opening date:' for you to write this information.

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 1 mg/ml + 50 mg/ml nasal spray, solution contains

- The active substances are xylometazoline hydrochloride and dexpanthenol.

Each ml of nasal spray, solution, contains 1 mg xylometazoline hydrochloride and 50 mg dexpanthenol.

One spray contains 0.1 ml of nasal spray, solution, 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 1 mg/ml + 50 mg/ml nasal spray, solution looks like and contents of the pack

Clear, colourless to slightly yellowish solution, free from particles.

Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is available in a bottle with a spray pump containing 10 ml of nasal spray, solution. Each bottle contains a minimum of 80 sprays.

Marketing Authorisation Holder

JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland

Manufacturer

Famar Health Care Services Madrid, S.A.U. Avda. Leganés, 62, Alcorcón, 28923 Madrid, Spain.

This medicines product is authorised in the Member States of the European Economic Area under the following names:

Bulgaria	Олинт Дуо 1 mg/ml + 50 mg/ml спрей за нос, разтвор
Croatia	Olynth Combo 1 mg/ml + 50 mg/ml sprej za nos, otopina
Cyprus	Hexarhinal Plus, 1 mg/ml+50 mg/ml ρινικό εκνέφωμα, διάλυμα
Czech Republic	Olynth Plus 1 mg/ml + 50 mg/ml nosní sprej, roztok
Estonia	Sudafed Xylospray DEX 1 mg/50 mg/ml ninasprei, lahus
Germany	Olynth Plus 0,1 % / 5 % Nasenspray, Lösung
Greece	Hexarhinal Plus, 1 mg/ml+50 mg/ml ρινικό εκνέφωμα, διάλυμα
Hungary	Actifed 1 mg/ml+50 mg/ml oldatos orrspray
Ireland	Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution
Latvia	Olydex 1 mg/50 mg/ml deguna aerosols, šķīdums
Lithuania	Olydex 1 mg/50 mg/ml nosies purškalas (tirpalas)
Poland	Sudafed Xylospray DEX, (1 mg + 50 mg)/ml, aerozol do nosa, roztwór
Portugal	Nasex Duo 1 mg/ml + 50 mg/ml solução para pulverização nasal
Romania	Olynth Duo 1 mg/ml+50 mg/ml spray nazal, soluție
Slovakia	Olynth Plus 1 mg/50 mg/ml nosová roztoková aerodisperzia
Slovenia	Olynth Combo 1 mg/ml + 50 mg/ml pršilo za nos, raztopina

This leaflet was last revised in September 2025