

SUDAFED[®]

DECONGESTANT

Liquid

Pseudoephedrine hydrochloride

- This medicine is used to provide relief from the symptoms of blocked nose or sinuses and catarrh associated with colds.
- This medicine is for use by children aged 6 years and over and can also be used by adults.
- **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 ▶*
 - If you are taking any **other medicines**. *See section 2 ▶*
- **Follow the dosage instructions carefully.** Children and adults need different amounts. *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 Decongestant Liquid is a medicine which is used to provide relief from the symptoms of blocked nose or sinuses and catarrh associated with colds. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion.

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

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.

X Do not use this medicine...

- If you have ever had a **bad reaction** to any of the ingredients of this medicine (listed in section 6).
- If you have **high blood pressure** or **heart disease**.

- If you have **diabetes**.
- If you have a **phaeochromocytoma** (a rare tumour that affects your heart rate and blood pressure).
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **severe kidney problems**.
- If you are taking **beta blockers** (used to treat **high blood pressure**).
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking **stimulants** or **appetite suppressants** or drugs used to treat **congestion** and **asthma** (*Sympathomimetic drugs*).
- If you are taking **any other cough and cold medicine**.
- **For children under 6 years old.**

If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Decongestant Liquid.**

Talk to your doctor or pharmacist...

- If you have **kidney** or **severe liver** problems.
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you are being treated for a **thyroid disorder**.
- If you have difficulty with passing water and / or an enlarged **prostate** (which may mean you need to pass water more often).
- If you are taking any **other medicines**, including:
 - **Tricyclic antidepressants** (drugs to treat **mood disorders**).
 - **Anticholinergic drugs** (drugs used to treat **cramps or spasms**)
 - **Antihypertensives** (drugs used to treat **high blood pressure** such as *guanethidine, methylodopa, adrenergic neurone blockers* and *beta blockers, debrisoquine, bretylum and betanidine*).
 - **Moclobemide** (used to treat **mood disorders**).
 - **Cardiac glycosides** (drugs used to **control heart rhythms or contractions** such as *digoxin*).
 - **Ergot alkaloids** (drugs used to treat **migraine** such as *ergotamine* and *methysergide*).
 - **Oxytocin** (drug used to help **contractions** during **childbirth**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.
If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

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! If you experience the following, stop taking this medicine immediately and contact your doctor:

- A feverish generalised erythema associated with pustules (See section 4)
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately. (See section 4).
- Reduction of blood flow to your optic nerve may occur with this medicine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. (See section 4).

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

- Each 5 ml of this medicine contains 3.5 g of **sucrose**. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.
- This medicine contains 5 mg benzoic acid in each 5 ml.
- Methyl hydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may occur after a few days.
- The colouring Ponceau 4R (E124) in this medicine may cause allergic reactions.
- This medicine contains 3.73 mg propylene glycol in each 5ml.
- This medicine contains 0.00007 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

turn over ▶



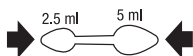
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3 How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not take more medicine than the label tells you to.
- Do not overfill the spoon.

There is a double-ended spoon in the pack.



i Children under 6 years

Do not give to children under 6 years.

i Adults and children aged 6 years and over.

| Age | Dose |
|---|--|
| Children 6-12 years | One large 5 ml spoonful every 4 - 6 hours, up to 4 times a day |
| Adults and children aged 12 years and over | Two large 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day |

- Leave at least 4 hours between doses.
- Do not take more than 4 doses in 24 hours.
- If symptoms persist or worsen stop use and talk to your doctor.
- Do not give to a child under 12 years old for more than 5 days without the advice of a doctor.

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 the last dose was taken at least 4 hours ago. **Do not** take a double dose.

4 Possible side-effects

Like all medicines, Sudafed Decongestant Liquid can have side-effects, although not everybody gets them.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack
- Stroke (weakness of the face, arms or legs, or speech problems).
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).
- Sudden onset of severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.
- Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (ischaemic optic neuropathy).

If you experience any of the following, stop using the medicine and talk to your doctor:

- Trouble passing water (especially in men with prostate problems).

Other effects which may occur include:

Very Common (may affect more than 1 in 10 people)

- Headache

Common (may affect up to 1 in 10 people)

- Difficulty sleeping, nervousness or dizziness
- Dry mouth or nausea

Other effects which may occur but it is unknown how often:

- Vomiting
- Anxiety, irritability, feeling jittery, or feelings of extreme happiness

- Restlessness or sleep disturbances.
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Pain when passing water
- High blood pressure
- Drowsiness
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)
- Pins and needles in your fingers and toes
- A tremor

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 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

Store below 25°C. Protect from light.

Keep this medicine out of the sight and reach of children. Keep the container tightly closed.

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

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 Decongestant Liquid is: Pseudoephedrine hydrochloride 30 mg per 5 ml.

Other ingredients are: Citric acid monohydrate, sucrose, glycerol, methyl hydroxybenzoate (E218), sodium benzoate (E211), Ponceau 4R (E124), raspberry flavour (Propylene Glycol E1520, Benzyl Alcohol, Sodium) and water.

What the medicine looks like

Sudafed Decongestant Liquid is a clear red liquid available in 100 ml amber glass bottles.

Marketing Authorisation holder:

McNeil Products Ltd, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. **turn over** ►

Manufacturer:

Famar Orléans, 5 avenue de Concy, 45071 Orléans, Cedex 2, France

This leaflet was last revised in August 2021.

Sudafed is a registered trade mark.

7 Information about treating cough and cold in children

It's normal for children to get 8 or more colds in a year. Because colds are caused by viruses, not bacteria, antibiotics don't help.

Here are simple steps to help your child who has a cough or cold.

If they are hot/feverish: Increase the amount of fluid your child normally drinks. Lower their temperature with a paracetamol or ibuprofen medicine which has doses for children.

For coughs: Coughing serves a purpose, it helps clear phlegm and mucus. Give the child plenty of warm clear fluids to drink.

To help with breathing: Plain saline nose drops / sprays can help with blocked noses.