

# SUDAFED<sup>®</sup>

## 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. These are shown in the tables. *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** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients.
- If you have **high blood pressure or heart disease**.
- If you have **diabetes**.
- If you have a **phaeochromocytoma** (rare tumour that affects your heart rate and blood pressure).
- If you have an **overactive thyroid**.
- If you have **closed angle 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 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.**

### **A** Talk to your doctor or pharmacist...

- If you have **kidney problems**.
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you have been diagnosed with an **intolerance to some sugars**.
- If you are taking any **other medicines**, including:
  - **Antimuscarinic / anticholinergic** drugs e.g.:
    - **Tricyclic antidepressants** (drugs to treat **mood disorders**).

- **Atropine** (used to treat some **eye conditions** and occasionally **bowel conditions**).
- **Antihypertensives** (drugs used to treat **high blood pressure** including *alpha and beta blockers*).
- **Sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat **congestion and asthma**).
- **Moclobemide** (used to **treat mood disorders**).
- **Cardiac glycosides** (drugs used to **control heart rhythms or contractions**) e.g. *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.**

### **A** If you are pregnant or breast-feeding

- Ask your doctor or pharmacist for advice before taking any medicine in pregnancy or whilst breast-feeding.

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

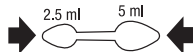
- Each 5 ml of this medicine contains 3.5 g of sucrose. This may be harmful to your teeth. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Methyl hydroxybenzoate 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.

## 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 use more than the stated dose shown in the table.
- Do not overfill the spoon.

There is a double-ended spoon in the pack.



### **i** Children under 6 years

Do not use this medicine in children under 6 years of age.

### **i** Children from 6 years and adults

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 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

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

**If anyone experiences any of the following stop using this medicine and seek immediate help:**

- Allergic reactions including skin rashes (which may be severe and include blistering and peeling of the skin) and itching.
- Allergic reactions to other medicines containing sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).
- Hallucinations and paranoid delusions.

**If anyone experiences any of the following, stop using this medicine and talk to your doctor:**

- An increased or irregular heartbeat, an increased awareness of the heartbeat (palpitations), high blood pressure.
- Restlessness and sleep disturbances.

**Other effects which may occur include:**

- Irritability, anxiety, excitability, nausea and sickness.
- Headache, difficulty in passing urine.

## 5 Storing this medicine

Store below 25°C. Protect from light.

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

Keep the container tightly closed.

Do not use after the end of the month shown as an expiry date on the packaging.

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 and water.

**What the medicine looks like**

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

**The Product Licence holder:**

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

**Manufacturer:**

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

**This leaflet was revised February 2010.**

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.

**McNeil**  
Products Ltd.

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