

# NON-DROWSY SUDAFED® DECONGESTANT 30 mg/5 ml SYRUP

Pseudoephedrine hydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Sudafed Decongestant Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advise.
- If any of the side-effects get serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

- What Sudafed Syrup is and what it is used for
- Before you take Sudafed Syrup
- How to take Sudafed Syrup
- Possible side-effects of Sudafed Syrup
- How to store Sudafed Syrup
- Contents of the pack and other information

## 1 What Sudafed Decongestant Syrup is and what it is used for

Non-Drowsy Sudafed Decongestant Syrup is used to provide relief from the symptoms of colds and flus including nasal congestion and blocked sinuses. It can also provide relief from nasal congestion when this is due to hayfever and similar allergic conditions. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion.

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



## 2 What you need to know before you take Sudafed Decongestant Syrup

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 take Sudafed Decongestant Syrup...

- If you are allergic to pseudoephedrine or any of the other ingredients of this medicine (listed in section 6).
- If you have high blood pressure or heart disease.
- If you are at risk of developing respiratory failure (which may occur if you have an underlying lung disease / condition e.g. pneumonia, build up of fluid on lungs).
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants.
- If you are taking the antibacterial agent furazolidone.
- If you are taking any other cough and cold medicine.
  - Do not give to children under 6 years.

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

### ! Warnings and Precautions. Before taking Sudafed Decongestant Syrup, talk to your doctor or pharmacist...

- If you intend to give to a child aged 6 to 12 years old.
- If you have liver or kidney problems.
- If you have diabetes or have been diagnosed with an intolerance to some sugars.
- If you have an overactive thyroid gland.
- If you have glaucoma (increased pressure in the eye).
- If you have prostate problems (difficulty with passing water or needing to pass water often).

- If you are taking any other medicines, including:
  - Decongestants, appetite suppressants, stimulants or sedatives.
  - Medicines for high blood pressure (e.g. methyl dopa).
  - Tricyclic antidepressants.
  - The antibacterial agent furazolidone.
  - Monoamine Oxidase Inhibitors (used to treat depression).
  - Halogenated anaesthetics agents (such as chloroform, cyclopropane, halothane, enflurane or isoflurane).

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.

### ! Pregnancy and Breast-feeding

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

### ! Driving and Using Machines

- Non-Drowsy Sudafed Decongestant Syrup has no or negligible influence on the ability to drive and use machines.

### ! 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.
- Methylhydroxybenzoate (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.

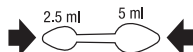
turn over ►

## 3 How to take Sudafed Decongestant Syrup

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

This medicine is not recommended for children under 6 years old.

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

Age	Dose
<b>Children 6-12 years</b>	<b>One 5 ml spoonful</b> every 4 - 6 hours, up to 4 times a day. Max. 20 ml in 24 hours.
<ul style="list-style-type: none"><li>■ Leave at least 4 hours between doses.</li><li>■ Do not give more than 4 doses (four 5 ml spoonfuls) in 24 hours.</li><li>■ Use only when simple measures have failed to provide adequate relief.</li><li>■ Do not give to a child under 12 years of age for more than 5 days without consulting your doctor.</li></ul>	
<b>Adults and children over 12 years</b>	<b>Two 5 ml spoonfuls</b> every 4 - 6 hours, up to 4 times a day. Max. 40 ml in 24 hours.
<ul style="list-style-type: none"><li>■ Leave at least 4 hours between doses.</li><li>■ Do not give more than 4 doses in 24 hours.</li><li>■ If symptoms persist talk to your doctor.</li><li>■ Patients with kidney or liver problems should talk to their doctor before taking this medicine. These patients should exercise caution when taking this product.</li><li>■ No dose adjustment is required for elderly patients.</li></ul>	

### **!** If you take more Sudafed Decongestant Syrup than you should

If anyone has too much contact a doctor or your nearest Accident & Emergency Department taking this leaflet and pack with you.

### **!** If you forget to take Sudafed Decongestant Syrup

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

Non-Drowsy Sudafed Decongestant Syrup 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 talk to your doctor:

- A few people have had hallucinations, but this is rare.
- Occasionally people get skin rashes that are sometimes itchy.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

- Increased heart beat (tachycardia), an increased awareness of the heart beat (palpitations).
- Restlessness, having trouble getting to sleep or bad dreams.

If you experience any side-effects not included in this leaflet or you are not sure about anything, talk to your doctor or pharmacist.

## 5 How to store Sudafed Decongestant Syrup

Do not store above 25°C. Keep in original container. Keep the product out of the reach and sight of children.

Keep the container tightly closed.

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

## 6 Contents of the pack and other information

**What's in this medicine?**

**The active ingredient in Non-Drowsy Sudafed Decongestant Syrup is:** Pseudoephedrine hydrochloride 30 mg per 5 ml.

**Other ingredients are:** Citric acid monohydrate, sucrose, glycerol, methyl hydroxybenzoate (E218), sodium benzoate (E211), Poncaeu 4R (E124), raspberry flavour and purified water.

**What Sudafed Decongestant Syrup looks like**

Non-Drowsy Sudafed Decongestant Syrup is a clear red liquid available in 100 ml bottles.

**The Product Authorisation holder:**

McNeil Healthcare (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland.

**Manufacturer:**

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

**This leaflet was revised July 2012.**

Sudafed is a registered trade mark.

**McNeil**  
Healthcare (Ireland) Ltd.

F309032  
11-0322