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 advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

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.

Do not take Sudafed Decongestant Syrup...

- If you have ever had a bad reaction (allergic reaction) to any of the ingredients (For a list of ingredients see section 6).
- If you have **severe kidney problems**.
- If you have **diabetes**.
- If you have **phaeochromocytoma** (rare tumour which 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 high blood pressure or heart disease.
- 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).
- If you have lung disease or persistent cough.
- If you are taking the antibacterial agent furazolidone.
- If you are taking other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).
- If you are taking any other cough and cold medicines.
- 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 have prostate problems (difficulty with passing water or needing to pass water often).
- If you intend to give to a **child aged 6 to 12 years old.**
- If you have epilepsy.
- If you have **blocked arteries** or **veins** (occlusive vascular disease).

Other medicines and Sudafed Decongestant Syrup

- If you are taking any other medicines, including:
  - *Antihypertensives* (drugs used to treat **high blood pressure**, such as guanethidine, reserpine, methyldopa, adrenergic neurone blockers and beta blockers, debrisoquine, bretylium and betanidine).
  - *Tricyclic antidepressants* (used to treat **mood disorders**).
  - *Halogenated anaesthetics agents* (such as chloroform, cyclopropane, halothane, enflurane or isoflurane).
  - *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)
  - *Anticholinergic drugs* (drugs used to treat **cramps** or **spasms** such as atropine).

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.**

If any of the following occur this product should be stopped:

- hallucinations
- restlessness
- sleep disturbances

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 advice 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.

Excipients warnings

- 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.

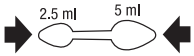
3 How to take Sudafed Decongestant Syrup

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.

turn over ▶

- Do not overfill the spoon. There is a double-ended spoon in the pack.



Children under 6 years

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

Children from 6 years and adults

Age	Dose
Children 6-12 years	**One 5 ml spoonful** every 4 - 6 hours, up to 4 times a day. Max. 20 ml in 24 hours.

- Leave at least 4 hours between doses.
- Do not give more than 4 doses (four 5 ml spoonfuls) in 24 hours.
- Use only when simple measures have failed to provide adequate relief.
- Do not give to a child under 12 years of age for more than 5 days without consulting your doctor.
- Parents or carers of children aged 6-12 years of age should seek medical attention if the child's condition deteriorates during treatment.

Adults and children over 12 years	**Two 5 ml spoonfuls** every 4 - 6 hours, up to 4 times a day. Max. 40 ml in 24 hours.

- Leave at least 4 hours between doses.
- Do not give more than 4 doses in 24 hours.
- If symptoms persist talk to your doctor.
- Patients with kidney or liver problems should talk to their doctor before taking this medicine. These patients should exercise caution when taking this product.
- No dose adjustment is required for elderly patients.

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

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

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

- Allergic reaction including skin rashes and itching, cross sensitivity may occur with other sympathomimetics.

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

- A few people have had hallucinations.
- A few men, especially men with prostate problems, may have trouble passing water.
- A few people may have restlessness or sleep disturbances.
- A fast or irregular heartbeat or an increased awareness of your heartbeat (palpitations).
- Delusions, epileptiform convulsions.

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)

- Dizziness, dry mouth
- Nausea (Feeling sick)
- Inability to sleep
- Nervousness

Other effects which may occur but it is unknown how often

- Agitation
- Feeling anxious
- Feeling of extreme happiness
- Irritability
- Difficulty sleeping
- High blood pressure
- Vomiting
- Feeling jittery
- Pain when passing urine
- Tremors
- Very high fever

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Sudafed Decongestant Syrup

Do not store above 25°C. Keep in original container.
Keep the product 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 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 this medicine contains

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), Ponceau 4R (E124), raspberry flavour and purified water.

What the medicine look like and content of the pack

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

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Sudafed is a registered trade mark.

McNeil Healthcare (Ireland) Ltd.

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Orleans - Artworks Center

Client	JNJ
Change request #	CRD URT/Pain XXX
Product	SUDAFED DECONGESTANT SYRUP 100ML IE
Component #	F310358
ATW version	11.3
Component type	Rolled Leaflet
Dimensions	160 x 210 mm
Drawing #	NOTC010
Safety code type & #	Datamatrix F310358
Client code	15/0039
Main font type	Bliss Regular
Minimum font size	8 pts - Horizontal scale 85%

Colours

Recto 1		Verso 1		Recto 2		Verso 2	
BLACK		BLACK		NA		NA	
PMS 300		PMS 300					

A print out of this artwork should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.