

Package leaflet: Information for the user

NON-DROWSY SUDAFED®

DECONGESTANT 30 mg/5 ml SYRUP

Pseudoephedrine hydrochloride

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 5 days.

What is in this leaflet

1. What Non-Drowsy Sudafed Decongestant Syrup is and what it is used for
2. What you need to know before you use Non-Drowsy Sudafed Decongestant Syrup
3. How to use Non-Drowsy Sudafed Decongestant Syrup
4. Possible side-effects
5. How to store Non-Drowsy Sudafed Decongestant Syrup
6. Contents of the pack and other information

1 What Non-Drowsy 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 hay fever 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 adults and children aged 6 years and over.

2 What you need to know before you use Non-Drowsy 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 use Non-Drowsy Sudafed Decongestant Syrup...

- If you have ever had a **bad reaction (allergic reaction)** to any of the ingredients (*listed in section 6*).
- If you have **severe acute (sudden) or chronic (long-term) kidney disease or kidney failure**.
- If you have **diabetes**.
- If you have a **pheochromocytoma** (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) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you have **lung disease or breathing problems**.
- If you are taking any **other cough and cold medicines**
- In children under 6 years

If any of these applies, **get advice from a doctor or pharmacist without using Non-Drowsy Sudafed Decongestant Syrup**.

If you experience the following, stop taking the product immediately and contact your doctor:

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

seek medical attention immediately (*see section 4*).

! Warnings and precautions

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).
- If you have **kidney or severe liver problems**.
- If you are being treated for a **thyroid disorder**.

Take special care with Non-Drowsy Sudafed Decongestant Syrup

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Non-Drowsy Sudafed Decongestant Syrup immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (*see section 4 "Possible side effects" for symptoms*).

! Other medicines and Non-Drowsy Sudafed Decongestant Syrup

Tell your doctor or pharmacist if your child is taking any other medicines including:

- **Antihypertensives** (drugs used to treat **high blood pressure**, such as *guanethidine, reserpine, methyl dopa, adrenergic neurone blockers, debrisoquine, bretylium and betanidine*).
- **Tricyclic antidepressants** (used to treat **mood disorders**).
- **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).
- **Stimulants or appetite suppressants** and drugs used to treat **congestion and asthma** (*sympathomimetic drugs*).

If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply, **talk to a doctor or pharmacist.**

! Pregnancy and Breastfeeding

■ 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

■ This medicine may cause drowsiness and reduce alertness. If affected, do not drive or operate machinery.

! Anti-doping tests

■ This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

! Non-Drowsy Sudafed Decongestant Syrup contains sucrose, methyl parahydroxybenzoate, Ponceau 4R, propylene glycol, benzyl alcohol, sodium and sodium benzoate

■ 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.

■ Methyl parahydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may occur after a few days.

■ This medicine contains Ponceau 4R (E124) which may cause allergic reactions

■ This medicine contains 3.73 mg propylene glycol in each 5ml dose.

■ This medicine contains 0.00007 mg benzyl alcohol in each 5 ml dose. 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”).

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

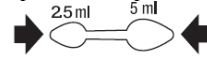
■ This medicine contains 5 mg sodium benzoate salt in each 5 ml.

3 How to use Non-Drowsy Sudafed Decongestant Syrup

Check the tables below to see how much medicine to use.

- For oral use only
- Always shake the bottle thoroughly before use
- Do not take more than the stated dose shown in the table
- Do not overfill the spoon

There is a double-ended spoon in the pack.



! Children under 6 years

This medicine should not be given to children under 6 years old.

! Adults and children aged 6 years and over under 6 years

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.
<ul style="list-style-type: none">■ 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.
<ul style="list-style-type: none">■ Leave at least 4 hours between doses.■ Do not give more than 4 doses in 24 hours.■ If symptoms persist or worsen talk to your doctor or pharmacist.	

! If you use more Non-Drowsy Sudafed Decongestant Syrup than you should

If anyone has too much contact a doctor or your nearest Accident & Emergency Department immediately taking this

leaflet and pack with you.

If you forget use Non-Drowsy 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, Non-Drowsy Sudafed Decongestant Syrup can have side-effects, although not everybody gets them.

! If you experience the following stop using this medicine and seek immediate help:

■ Stop using Non-Drowsy Sudafed Decongestant Syrup immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures
- changes in vision

■ 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 stomach pains, passing blood in your stools or bleeding from your back passage and diarrhoea.

■ 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 reaction including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.

■ Hallucinations, paranoid delusions or fits.

! If you experience the following stop using this medicine and talk to your doctor

■ A fast or irregular heartbeat or an increased awareness of your heartbeat (palpitations).

■ Trouble passing water (especially men with prostate problems).

■ Restlessness or sleep disturbances.

■ Reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

! 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)

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

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

■ Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

■ Agitation, anxiety, irritability, feeling jittery or feelings of extreme happiness

■ High blood pressure

■ Vomiting

■ Pain when passing urine

■ Tremors

■ Heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina)

■ Tingling or numbness of the hands or feet (pins and needles)

■ Very high fever

■ Inflammation of the colon due to insufficient blood supply (ischaemic colitis)

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 Website: www.hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Non-Drowsy 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.

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 Contents of the pack and other information

What Non-Drowsy Sudafed Decongestant Syrup 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 (containing propylene glycol E1520, benzyl alcohol and sodium) and purified water.

What the medicine like and the contents of the pack

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

The Marketing Authorisation holder:

JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland. **Manufacturer:** Delpharm Orleans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

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