

Package leaflet: Information for the user
Non-drowsy Sudafed Decongestant
60mg film-coated Tablets
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

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2. What you need to know before you use Non-Drowsy Sinutab Tablets
3. How to use Non-Drowsy Sudafed Decongestant Tablets
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1 What Non-Drowsy Sudafed Decongestant Tablets is and what it is used for

Non-Drowsy Sudafed Decongestant Tablets are a medicine used to provide relief from cold, flu and allergy symptoms such as blocked sinuses, stuffy nose and catarrh. The tablets contain pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion.

This medicine is for use by adults and children aged 12 years and over.

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

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 use this medicine...

- If you have ever had a **bad reaction (allergic reaction)** to pseudoephedrine or any of the other ingredients (*listed in section 6*).
- If you have **severe acute (sudden) or chronic (long-term) kidney problems**.
- 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 12 years.

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

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 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**.

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 Tablets, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Non-Drowsy Sudafed Decongestant Tablets, 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 Tablets. If you develop sudden loss of vision, stop taking Non-Drowsy Sudafed Decongestant Tablets and contact your doctor or seek medical attention immediately (*see section 4*).

Other medicines and Non-Drowsy Sudafed Decongestant Tablets

- Tell your doctor or pharmacist if you are taking any **other medicines**, including:
 - **Antihypertensives** (drugs to treat **high blood pressure** such as *guanethidine, methyldopa, adrenergic neurone blockers, debrisoquine, bretylium, reserpine* and *betanidine*).
 - **Oxytocin** (drug used to help **contractions** during childbirth).
 - **Moclobemide** (used to treat **mood disorders**).
 - **Cardiac glycosides** (drugs used to control **heart rhythms** or **contractions** e.g. *digoxin*).
 - **Ergot alkaloids** (used to treat **migraine** such as *ergotamine* and *methysergide*).
 - **Tricyclic antidepressants** (used to treat **mood disorders**).
 - **Cholestyramine** (to **lower blood cholesterol**).
 - **Metoclopramide** and **domperidone** (to treat **nausea** and **vomiting**).
 - **Stimulants or appetite suppressants** and drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).
 - **Anticoagulants** (to **thin the blood** such as *warfarin*).
 - **Oral contraceptives** (“the pill”).
 - **Anticonvulsants** (drugs used to treat **epilepsy**).
 - **Anticholinergic drugs** (drugs used to treat **cramps** or **spasms** such as *atropine*).
 - **flucloxacillin** (an antibiotic) due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe kidney impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- 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**.

Take special care with Non-Drowsy Sudafed Decongestant Tablets

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 tablets 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).

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 using 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 Tablets contain lactose

■ This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to use Non-Drowsy Sudafed Decongestant Tablets

Check the tables that follow to see how much medicine to take

- For oral use only.
- Do not take more than the stated dose shown in the tables.
- Take with a glass of water.

Children under 12 years

This medicine should not be given to children under 12 years old.

Adults and children aged 12 years and Over

Age	Dose
Adults and children aged 12 years and over	Swallow 1 tablet every 4-6 hours up to 4 times a day

- Leave at least 4 hours between doses.
- Do not take more than 4 tablets in 24 hours.
- If symptoms persist or worsen talk to your doctor or pharmacist.

If you use more Non-Drowsy Sudafed Decongestant Tablets 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 to use Non-Drowsy Sudafed Decongestant Tablets

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 Tablets can have side-effects although not everybody gets them.

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

Stop using Non-Drowsy Sudafed Decongestant tablets 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 any of 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 not known 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 Tablets

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

Do not use Sudafed Tablets after the expiry date which is stated on the carton label and blister after "Expiry". The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package to protect from light.

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 Tablets contain

The active ingredient in Non-Drowsy Sudafed Decongestant Tablets is:

Pseudoephedrine hydrochloride 60 mg per tablet.

Other ingredients are: Lactose monohydrate, cellulose microcrystalline, pregelatinized maize starch, silica colloidal anhydrous, magnesium stearate.

Film-coat: Opadry OY-9473 (Opadry OY-9473 contains hypromellose, red iron oxide (E172), talc and macrogol 400).

What the medicine looks like and contents of the pack

Non-Drowsy Sudafed Decongestant Tablets are reddish brown film-coated tablets, embossed SUDAFED, available in packs of 12 tablets.

Marketing Authorisation holder:

JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland.

Manufacturer: JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France

This leaflet was revised in July 2024.

Sudafed is a registered trade mark.