

Package leaflet: Information for the user

Non-Drowsy Sudafed® Decongestant 60mg Film-Coated Tablets (pseudoephedrine hydrochloride)

Your medicine is available using the above name but will be referred to as 'Sudafed Tablets' throughout this leaflet.

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 Sudafed Tablets are and what are they used for
2. What you need to know before you use Sudafed Tablets
3. How to use Sudafed Tablets
4. Possible side-effects
5. How to store Sudafed Tablets
6. Contents of the pack and other information

1. What Sudafed Tablets are and what are they used for

Sudafed 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 Sudafed 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 kidney problems**.
- If you have **diabetes**.
- If you have a **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) 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 Sudafed 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).

Other medicines and Sudafed Tablets

- If you are 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 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 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.

Sudafed 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 Sudafed Tablets

Check the table that follows to see how much medicine to take.

- For oral use only.
- Do not take more than the stated dose shown in the table.
- 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 Sudafed 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 Sudafed 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, Sudafed 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:

- 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).
- 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.

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:

- Agitation, anxiety, irritability, feeling jittery or feelings of extreme happiness
- High blood pressure
- Vomiting
- 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: medsaftey@hpra.ie
By reporting side-effects, you can help provide more information on the safety of this medicine.

5. How to store Sudafed Tablets

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and blister strips after EXP. 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 Sudafed Tablets contain

The active ingredient in Sudafed Tablets is pseudoephedrine hydrochloride. Each film-coated tablet contains 60mg pseudoephedrine hydrochloride.

Other ingredients are:

lactose, cellulose microcrystalline, maize starch, silica, magnesium stearate, hypromellose, red iron oxide (E172), talc and polyethylene glycol.

What the medicine looks like and contents of the pack

Sudafed Tablets are reddish-brown, circular, biconvex, film-coated, embossed 'SUDAFED' on one side and plain on the other.

Your medicine is available in blister pack containing 12 film-coated tablets.

Manufacturer

Manufactured by: Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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Is this leaflet hard to see or read?

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(Regulatory)