

NON-DROWSY SUDAFED®

60mg FILM-COATED TABLETS

Pseudoephedrine hydrochloride

- This medicine is used to help clear cold, flu and allergy symptoms such as blocked sinuses, stuffy nose and catarrh.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
 - There are some people who should not take this medicine. *To find out if you are one of them see section 2* ▶
 - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
- **Speak to your doctor or pharmacist:**
 - If you suffer from any of the conditions mentioned in section 2. See section 2 ▶
 - If you are taking any **other medicines**. See section 2 ▶
- **Follow the dosage instructions carefully.** See section 3 ▶
- **Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet; you might need it again.

1 What the medicine is 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 Before taking this medicine

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 any of the ingredients (for a list of ingredients see section 6).
 - 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 have **very high blood pressure or severe heart disease**.
 - 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 any of these apply to you, **get advice from a doctor or pharmacist before using Non-Drowsy Sudafed Decongestant Tablets.**
- ### ⚠ Talk to your doctor or pharmacist...
- If you have **liver or kidney problems**.
 - If you have **high blood pressure or heart disease**.

■ If you have **diabetes** or have been diagnosed with an **intolerance to some sugars**.

■ If you have **epilepsy**.

■ If you are taking any **other medicines**, including:

■ **Antihypertensives** (drugs used to treat **high blood pressure**, such as guanethidine, reserpine,

methyldopa, alpha and beta blockers,

debrisoquine, bupropion and betandine).

■ **Tricyclic antidepressants** (used to treat **mood disorders**).

■ **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.**

■ **If you are pregnant or breast-feeding:**

■ Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

■ **Some of the ingredients can cause problems**

■ 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.

turn over ▶



3 How to take this medicine

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 below.
- Take with a glass of water.

i Children under 12 years old

Non-Drowsy Sudafed Decongestant Tablets are not recommended for children under 12 years old.

i Adults and children aged 12 years and over

Age	Dosage
Adults and children aged 12 years and over	Swallow 1 tablet every 4 - 6 hours up to 4 times a day
<ul style="list-style-type: none">■ 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.	

⚠ If anyone has too much

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 the medicine

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 Tablets 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:

- Restlessness, having trouble getting to sleep or bad dreams.
- Tremors, epileptiform convulsions.
- High fever.

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

5 Storing this medicine

Keep the product out of the reach and sight 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 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 Further information

What's in this medicine?

The active ingredient in Non-Drowsy Sudafed Decongestant Tablets is: Pseudoephedrine hydrochloride 60 mg per tablet.

Other ingredients are: Lactose monohydrate, cellulose microcrystalline, pregelatinised 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

Non-Drowsy Sudafed Decongestant Tablets are reddish brown film-coated tablets, embossed SUDAFED, available in packs of 12 or 24 tablets.

Product Authorisation holder:

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

Manufacturer: Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised January 2011.

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Healthcare (Ireland) Ltd.

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