

SUDAFED®

DECONGESTANT

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:**
 - 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 ►*

- 1 -

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

Sudafed Decongestant Tablets is 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** to any of the ingredients of this medicine (see section 6).

- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**.
- If you have a **phaeochromocytoma** (a rare tumour that 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 severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- 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 are taking **stimulants** or **appetite suppressants** or drugs used to treat **congestion** and **asthma** (*Sympathomimetic drugs*).
- If you are taking **any other cough and cold medicine**.
- **For children under 12 years old.**

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

turn over ►

⚠️ Talk to your doctor or pharmacist...

- If you have **kidney** or **severe liver** problems.
- If you have **blocked arteries** or **veins** (occlusive vascular disease).
- If you are being treated for a **thyroid disorder**.
- If you have difficulty with passing water and / or an enlarged **prostate** (which may mean you need to pass water more often).
- If you are taking any **other medicines**, including:
 - *Antihypertensives* (drugs used to treat **high blood pressure** such as *guanethidine*, *methyl dopa*, *adrenergic neurone blockers* and *beta blockers*, *debrisoquine*, *bretylum* and *betanidine*).
 - *Tricyclic antidepressants* (used to treat **mood disorders**).
 - *Anticholinergic drugs* (drugs used to treat **cramps** or **spasms**)
 - *Moclobemide* (used to treat **mood disorders**).
 - *Cardiac glycosides* (drugs used to **control heart rhythms** or **contractions** such as *digoxin*).
 - *Ergot alkaloids* (drugs used to treat

migraine such as *ergotamine* and *methysergide*).

- *Oxytocin* (drug used to help **contractions** during **childbirth**).

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 experience the following, stop taking this medicine immediately and contact your doctor:

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

medical attention immediately. (See section 4).

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 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).

⚠️ If you are pregnant or breastfeeding

If you are pregnant, or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

⚠️ 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.

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 medicine than the label tells you to.
- Take with a glass of water.

i Children under 12 years
Do not give to children under 12 years old.

i 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 doses in 24 hours.
- If symptoms persist or worsen stop use and talk to your doctor.

! If anyone has too much
If anyone has too much contact a doctor or your nearest Accident & Emergency Department (Casualty) 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

Like all medicines, Sudafed Decongestant Tablets can have side-effects, although not everybody gets them.

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

- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack.
- Stroke (weakness of the face, arms or legs, or speech problems).
- 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 onset of 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 reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.
- Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (ischaemic optic neuropathy).

If you experience any of the following, stop using the medicine and talk to your doctor:

- Trouble passing water (especially in men with prostate problems).

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)

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

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).
- Vomiting
- Anxiety, irritability, feeling jittery or feelings of extreme happiness
- Restlessness or sleep disturbances.
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Pain when passing water
- High blood pressure
- Drowsiness
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)
- Pins and needles in your fingers and toes
- A tremor

Stop using 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

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing this medicine

Store below 30° C in the original package to protect from moisture.

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 after 'Expiry'. 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 Further information

What's in this medicine?

The active ingredient in Sudafed

Decongestant Tablets is: Pseudoephedrine hydrochloride 60 mg per tablet.

Other ingredients are: Lactose, microcrystalline cellulose, maize starch, silica, magnesium stearate, hypromellose, polyethylene glycol, talc and red iron oxide (E172).

What the medicine looks like

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

Marketing Authorisation holder:

McNeil Products Ltd, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer:

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This leaflet was last revised in April 2024.

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