

SUDAFED®

CONGESTION & HEADACHE RELIEF

DAY & NIGHT Capsules

Paracetamol, Caffeine & Phenylephrine

- This medicine is used for the relief of symptoms associated with colds and flu, including stuffy nose, headache, fever, sore throat, aches and pains.
- This medicine is for use by adults, the elderly and children aged 16 years and over.
- **Do not use this medicine:**
 - There are some people who should not use 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 do not feel better or if you feel worse after 3 days.**
 - **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.** There are different capsules for day and night time doses. *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

Sudafed Congestion & Headache Relief Day & Night Capsules are used for the relief of symptoms associated with colds and flu, including stuffy nose, headache, fever, sore throat, aches and pains.

The Day Capsules can also relieve tiredness and drowsiness.

The Night Capsules contain paracetamol, an analgesic and antipyretic which helps to relieve pain and fever and phenylephrine hydrochloride, which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

The Day Capsules contain paracetamol and phenylephrine hydrochloride (as above) but also contain caffeine, which provides relief from fatigue (tiredness) associated with colds and flu. Caffeine can also increase pain relief from paracetamol.

This medicine is for use in adults, the elderly and children aged 16 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.

X Do not use this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If you have **severe heart disease or cardiovascular disorder(s).**
- If you have **high blood pressure.**
- If you have an **overactive thyroid gland.**
- If you have an **enlarged prostate.**
- If you have a **history of stomach ulcers.**

- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs). If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Congestion & Headache Relief Day & Night Capsules.**

A Talk to your doctor or pharmacist...

- If you have **liver or kidney problems.**
- If you are taking **alcohol.**
- If you have a **blood circulation problem** (including Raynaud's Phenomenon).
- If you suffer from **diabetes.**
- If you are taking any **other medicines,** including:
 - **tricyclic antidepressants** (drugs used to treat **mood disorders**).
 - **barbiturates** (a kind of **sleeping tablet**).
 - **sympathomimetic drugs** (*stimulants* or *appetite suppressants* and drugs used to treat **congestion and asthma**).
 - **antihypertensives** (drugs used to treat **high blood pressure** such as beta blockers or vasodilators).
 - **colestyramine** (used to **lower blood cholesterol**).
 - **metoclopramide or domperidone** (used to treat **nausea and vomiting**).
 - **anticoagulants** (drugs used to **thin the blood,** such as warfarin).
 - **flucloxacillin** (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 renal 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 pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

A 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.

A CONTAINS PARACETAMOL

- **Do not take anything else containing paracetamol while taking this medicine.**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take this medicine

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

- For oral use only.
- Swallow the capsules whole with water. Do not chew.
- Do not take more medicine than the label tells you to.
- **Children under 16 years old**
Do not give to children under 16 years old.

turn over ▶

i Adults, the elderly and children aged 16 years and over

Age	Dosage
Adults, the elderly and children aged 16 years and over	Day time: 2 red / yellow Day Capsules every 4 - 6 hours, up to 3 times a day. Night time: 2 dark blue / light blue Night Capsules to be taken at night.

- Leave at least 4 to 6 hours between doses.
- Do not take more than 6 Day Capsules and 2 Night capsules (4 doses) in 24 hours.
- Do not take for more than 3 days, unless advised by your doctor.
- If you do not get better, talk to your doctor. The Day time capsules contain caffeine and so may disrupt sleep if taken at night.

! If anyone has too much

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet 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

Sudafed Congestion & Headache Relief Day & Night Capsules can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

- Allergic reactions such as skin rash.
- Raised blood pressure with headache, vomiting and palpitations.
- An increase or decrease in heart rate.
- You may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

Other effects which may occur include:

- Nausea.
- Difficulty sleeping.
- Tingling and coolness of the skin.

Very rare cases of serious skin reactions have been reported.

Side effects with unknown frequency:

Problems or pain passing urine. This is more likely to occur in men with an enlarged prostate gland.

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

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use after the end of the month shown as an expiry date on the packaging.

6 Further information

What's in this medicine?

The active ingredients in Sudafed Congestion & Headache Relief Day & Night Capsules are: **Day Capsule:** Paracetamol 500 mg, caffeine 25 mg and phenylephrine hydrochloride 6.1 mg per capsule.

Night Capsule: Paracetamol 500 mg and phenylephrine hydrochloride 6.1 mg per capsule. **Other ingredients are:** **Day Capsules:** Maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the colours quinoline yellow (E104), titanium dioxide (E171), patent blue V (E131) and erythrosine (E127).

Night Capsules: Maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the colours titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

What the medicine looks like

Sudafed Congestion & Headache Relief Day & Night Capsules are red / yellow capsules (Day) and dark blue / light blue capsules (Night) and are available in packs containing 12 Day Capsules and 4 Night Capsules.

Marketing Authorisation holder and manufacturer:

Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK.

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

This leaflet was last revised in December 2022.

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