

# 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.

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 (Hypertension)**.
- If you are taking medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (e.g. atenolol).
- If you have severe hepatic impairment.
- If you have severe renal impairment.
- If you have an **overactive thyroid gland**.
- If you have an **enlarged prostate**.
- If you have diabetes.
- If you have pheochromocytoma.
- If you have glaucoma, including closed angle glaucoma.
- If you are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's), or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid.
- If you are taking tricyclic antidepressants such as imipramine, amitriptyline.
- If you are taking medicines belonging to a

**turn over** ►



group called sympathomimetic amines such as dopamine, epinephrine.

If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Congestion & Headache Relief Day & Night Capsules.**

**! During treatment with this medicine, tell your doctor straight away...**

■ If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

**! Talk to your doctor or pharmacist...**

- If you have **liver** or **kidney problems**.
- If you are pregnant or breast-feeding.
- If you are taking **alcohol**.
- If you are dehydrated.
- If you have difficulty passing urine.
- If you have a **blood circulation problem** (including Raynaud's Phenomenon).
- If you have a blood condition called Haemolytic anaemia.
- If you have genetic conditions such as Gilbert's syndrome or Glucose-6-phosphate dehydrogenase deficiency.
- If you have Glutathione deficiency.
- If you are taking any **other medicines**, including:
  - *barbiturates* (a kind of **sleeping tablet**).
  - *sympathomimetic drugs (stimulants or appetite suppressants* and drugs used to treat **congestion** and **asthma**).
  - *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).
- *probenacid* (drugs to treat gout).
- *anti-arrhythmics* (drugs to treat irregular heartbeats e.g. digoxin).
- *ergot alkaloids* (drugs to treat severe headaches)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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.**

**! Pregnancy, breast-feeding and fertility**

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not take this medicine.

**! CONTAINS PARACETAMOL**

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

Information about some of the ingredients in 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.**

**Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.**

- 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.

## **Adults, the elderly and children aged 16 years and over**

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

Like all medicines, Sudafed Congestion & Headache Relief Day & Night Capsules can cause side effects, although not everybody gets them. **Stop taking the medicine immediately and see your doctor or pharmacist.**

### **Rare side effects are:**

- Allergic reactions such as skin rash.
- Fast, slow or irregular heartbeat (palpitations).

- Eye disorders such as dilated pupils, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma.

### **Very rare side effects are:**

- Blood and lymphatic system disorders such as leukopenia, neutropenia and pancytopenia.
- A severe allergic reaction known as anaphylaxis.
- Problems with your liver.
- Skin issues such as rashes, severe itching, sweating, hives.
- Purpura (small blood vessels leak blood under the skin).
- Bronchospasm (muscles in your chest tighten).
- Angioedema (swelling of the skin caused by build-up of fluid).
- Toxic epidermal necrolysis.
- Stevens-Johnson syndrome (rare condition arising from over reaction of the immune system).
- Kidney and urinary disorders.

### **Frequency not known (frequency cannot be estimated from the available data):**

- Tingling and coolness of the skin.
- Difficulty sleeping (insomnia) (Day capsule only).
- Nausea (feeling sick) (Day capsule only).
- Problems or pain passing urine. This is more likely to occur in men with an enlarged prostate gland.
- Feeling nervous (Day capsule only).
- Feeling dizzy (Day capsule only).
- A rise in blood pressure.
- Headache.
- Stomach disorders (nausea, vomiting, diarrhoea)
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

### **Reporting of side-effects**

If you get any side-effects, talk to your doctor or pharmacist. 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](http://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.

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