

Please note that there are currently 2 leaflets available for the **SUDAFED SINUS MAX STRENGTH CAPSULES, HARD [PL 12063/0067]**. Following SNAS 4093, a type IB variation to add a new pack size of 12 capsules to the already approved 16 pack size. Consequently, the PIL and label have been updated.

Both leaflets are applicable to the same product licence number namely, PL 12063/0067.

The information contained within each leaflet is identical apart from the pack information and the date of revision, both of which are stated under “*What the medicine looks like*” of Section 6 (Contents of the pack and other information).

1. In PIL 1 (page 2):

Pack information: “**Sudafed Sinus Max Strength Capsules** are red/blue capsules available in packs of 16 capsules.”

Date of revision: “**This leaflet was revised January 2023.**”

2. In PIL 2 (page 2):

Pack information: “**Sudafed Sinus Max Strength Capsules** are red/blue capsules available in packs of 12 capsules.”

Date of revision: “**This leaflet was revised March 2024.**”

This is a combined PDF of both leaflets.

SUDAFED®

SINUS

MAX STRENGTH Capsules

Paracetamol, Caffeine & Phenylephrine

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

- This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it.
 - Keep this leaflet as 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.
 - You must talk to a doctor if you do not feel better or if you feel worse after 3 days

What is in this leaflet?

1. What is Sudafed Sinus Max Strength Capsules and what is it used for
2. What you need to know before you take Sudafed Sinus Max Strength Capsules
3. How to take Sudafed Sinus Max Strength Capsules
4. Possible side-effects
5. How to store Sudafed Sinus Max Strength Capsules
6. Contents of the pack and other information

1 What is Sudafed Sinus Max Strength Capsules and what is it used for

Sudafed Sinus Max Strength Capsules help relieve the symptoms of pain and congestion caused by sinusitis, which include stuffy nose, blocked sinuses, headache, fever, aches and pains.

The capsules contain paracetamol, an analgesic and antipyretic which helps to relieve pain and fever, caffeine, a stimulant to help combat tiredness and to help increase the pain relief, and phenylephrine hydrochloride, which is a decongestant.

This medicine is for use by adults, the elderly and children aged 16 years and over.

2 What you need to know before you take Sudafed Sinus Max Strength Capsules

This medicine is suitable for most adults and children aged 16 years and over 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 are **allergic** to paracetamol, caffeine, phenylephrine or any of the other ingredients listed in section 6.
- If you have **high blood pressure**.
- If you have **severe heart disease or circulatory problems**.
- If you have an **overactive thyroid**.
- If you have a history of **stomach ulcers**.
- If you have an **enlarged prostate**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- **In children under 16 years old**.
- If you are taking tricyclic antidepressants, such as imipramine, amitriptyline.

If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Sinus Max Strength Capsules**.

⚠ Please see your doctor or pharmacist before taking this medicine if you:

- are pregnant or breastfeeding
- suffer from kidney or liver problems, including alcoholic liver disease or have alcohol dependence

- have diabetes
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.

⚠ Other medicines and Sudafed Sinus Max Strength Capsules

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines
 - medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as *colestyramine*
 - medicines to control feeling sick or being sick such as *metoclopramide* or *domperidone*
 - medicines called *anti-coagulants*, which are used to thin the blood such as *warfarin* or other *coumarins* - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
 - *barbiturates* (for epilepsy or to help you sleep), such as *phenobarbitone*
 - medicines to treat migraines such as *ergotamine* or *methysergide*
 - medicines to lower blood pressure, treat heart or circulatory problems such as *beta blockers* (e.g. atenolol) or *vasodilators* (e.g. hydralazine)
 - other decongestant drugs such as *ephedrine* or *xylometazoline*.
 - *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 pregnant or breast-feeding:

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

⚠ Sudafed Sinus Max Strength Capsules contains paracetamol.

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

Sudafed Sinus Max Strength Capsules with food, drink and alcohol

- Do not drink alcohol (beer, wine, spirits etc) while taking this product.

Information about some of the ingredients in this medicine

This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'.

3 How to take this medicine

Check the table below 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. Do not chew.

⚠ Children and adolescents

Do not give to children under 16 years.

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

Age	Dosage
Adults, the elderly and children aged 16 years and over	Two capsules every 4 to 6 hours as required.

- Do not take more than eight capsules (4 doses) in any 24 hours period.
- Leave at least 4 to 6 hours between doses.
- If you do not get better, talk to your doctor or pharmacist.
- Do not take for more than 3 days unless advised by your doctor.

⚠ Taking this medicine with food and drink:

You should avoid too much caffeine in drinks like coffee and tea. If you are also consuming other medicines or food that contains caffeine (coffee, tea, cola drinks, chocolate) you may have a high caffeine intake and might have difficulty sleeping, start shaking and/or an uncomfortable feeling in the chest.

⚠ If anyone has too much

Talk to a doctor as 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 Sinus Max Strength Capsules can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

Unknown side-effects are:

- bronchospasm
- restlessness, anxiety, nervousness, irritability, agitation

Rare side-effects are:

- allergic reactions such as skin rash
- nausea (feeling sick) or vomiting (being sick) or diarrhoea
- headache, tremor, dizziness
- difficulty sleeping (insomnia)
- fast, slow or irregular heart beat (palpitations)
- high blood pressure
- glaucoma
- problems or pain passing urine
- sudden weight loss, loss of appetite and yellowing of the eyes and skin

More rarely, the following side-effects can happen:

you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

Very rare cases of serious skin reactions have been reported.

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 How to store Sudafed Sinus Max Strength Capsules

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.

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's in this medicine?

The active ingredients in Sudafed Sinus Max Strength

Capsules are: 500 mg Paracetamol, 25 mg Caffeine and 6.1 mg Phenylephrine hydrochloride per capsule.

Other ingredients are: Maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, talc, gelatin, titanium dioxide (E171), quinoline yellow (E104), Patent Blue V (E131), erythrosine (E127) and indigo carmine (E132).

What the medicine looks like

Sudafed Sinus Max Strength Capsules are red/blue capsules available in packs of 16 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 revised January 2023.

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MAX STRENGTH Capsules

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

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