SUDAFED®

Paracetamol, Caffeine & Phenylephrine

Sudafed Congestion & Headache Relief 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. 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 use this medicine.

See Section 2 to find out if you are one of them >
If you have ever had a bad reaction to any of the ingredients. See Section 6 for the list of ingredients

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 ► Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

What the medicine is for

Sudafed Congestion & Headache Relief 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 and children aged 12 years and over.

Before taking this medicine

This medicine is suitable for most adults and children aged 12 years and over but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

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 ever had a bad reaction to paracetamol or any of the other ingredients. See section 6 for full list of ingredients.

If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).

In children under 12 years old If any of these apply to you, get advice from a doctor or pharmacist without using Sudafed Congestion & Headache Relief Max Strength Capsules.

If you have liver or kidney problems.
 If you have alcohol dependence.
 If you have a blood circulation problem

(including Raynaud's Phenomenon). If you suffer from **diabetes**.

If you are taking alcohol.

If you are taking actions:

If you are taking any other medicines, including:

barbiturates (a kind of sleeping tablet).

tricyclic antidepressants (drugs used to treat mood disorders).

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) 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)

vasodilators (used to treat high blood pressure, heart failure or angina). 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.

etamo

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

How to take this medicine

Check the table below to see how much edicine to take.

For oral use only.

children aged 12

Do not take more medicine than the label tells you to.

Take with a glass of water. Do not chew.

Children under 12 vears

Do not give to children under 12 years old.

Adults and children aged 12 years and over

as required, to a maximum of

Age Dosage Adults and 2 Capsules every 4 hours

years and over 4 doses in any 24 hours Do not take more than 8 capsules in 24 hours.

Leave at least 4 hours between doses

If you do not get better, talk to your doctor.

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.

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.

Possible side-effects

Sudafed Congestion & Headache Relief Max Strength 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 seek immediate help:

Allergic reactions including skin rashes (which may be severe and include blistering or peeling of the skin) and itching. f you experience any of the following, stop using he medicine and talk to your doctor:

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.

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

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. 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 the product 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.

Further information

in this medici

The active ingredients in Sudafed Congestion & Headache Relief 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).

Sudafed Congestion & Headache Relief Max Strength Capsules are red/blue capsules available in packs of 16 capsules. Marketing Authorisation holder and Manufacturer: Wrafton Laboratories Limited, Braunton, North Devon, EX33 2DL, UK

Distributor: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

This leaflet was revised March 2014. Sudafed is a registered trade mark.

McNeil)

13-0057 274<u>4508</u>