

SUDAFED[®] MUCUS RELIEF TRIPLE ACTION Cold & Flu Tablets

Paracetamol, Guaifenesin & 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.

1. What is this medicine and what is it used for?

This medicine contains:

- paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- guaifenesin which is an expectorant to help loosen phlegm
- phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

2. Is this medicine suitable for you?

Do not take this medicine if you:

- are allergic to paracetamol, guaifenesin, phenylephrine or any of the other ingredients
- have a serious heart condition
- have high blood pressure (hypertension)
- have diabetes
- have an overactive thyroid
- have glaucoma
- have difficulty passing urine
- 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
- are currently taking other decongestant drugs or stimulants (e.g. ephedrine, amfetamines and xylometazoline).

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

- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have angina
- have an enlarged prostate gland, as this may cause more difficulty in passing urine.

If you are taking any of the following medicines please see your doctor:

- 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
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyl dopa)
- beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine)
- phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)
- if you are going to have a general anaesthetic as this may cause changes in heart rhythm.

Contains paracetamol.

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

2. Is this medicine suitable for you? (Continued)

Other important information:

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

If you are taking medication, or are under medical care, consult your doctor before using this medicine.

Long term use of this product is not recommended.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew. Adults, the elderly and children 12 years and over: 2 tablets every 4 hours, as required. Do not take more than 8 tablets (4 doses) in any 24 hour period.

Do not give to children under 12 years.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

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.

4. Possible side-effects

Most people do not have any side-effects while taking this medicine. However, if you experience any of the following side-effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side-effects are:

- allergic reactions such as skin rash
- stomach upsets
- tingling or coolness of the skin
- a faster or slower heart beat
- difficulty sleeping (insomnia)
- nervousness, tremors or convulsions
- a rise in body temperature

■ a rise in blood pressure with headache, vomiting (being sick) and irregular heartbeat (palpitations).

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

5. How to store your medicine

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of the month. Do not store above 25°C.

6. What is in this medicine?

Each white, capsule-shaped tablet contains the active ingredients: paracetamol 250 mg, guaifenesin 100 mg and phenylephrine hydrochloride 5 mg.

The other ingredients are: microcrystalline cellulose, stearic acid, povidone, hypromellose and polyethylene glycol.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK.

The distributor is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.