

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 (listed in section 6)
- have a serious heart condition
- have high blood pressure (hypertension)
- have diabetes
- have an overactive thyroid
- have glaucoma, including closed angle 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 taking beta-blocking drugs
- are currently taking other decongestant drugs or stimulants (e.g. ephedrine, amfetamines and xylometazoline)

- are taking a cough medicine called a cough suppressant.

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 diabetes
- have phaeochromocytoma
- have a very bad cough or asthma. See your doctor if your cough lasts for more than 5 days or comes back, or if you have a fever, rash or a headache which won't go away
- 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
- have severe stomach or intestinal problems
- suffer with phenylketonuria, a rare, inherited metabolic disorder.

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)
- aspirin or other NSAIDs (non-steroidal anti-inflammatory drugs)
- medicines to treat migraine (e.g. ergotamine and methylsergide)
- zidovudine as this might cause blood problems (low white blood cell count)
- 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 blood or urine tests as taking this medicine may affect the results

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

- 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.

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. Do not use for longer than 5 days, except on medical advice
- This medicine should only be used if you have all of the following symptoms - pain and/or fever, a blocked nose and a chesty cough
- Use medicines which will only treat the symptoms you have
- Do not take with other flu, cold or decongestant products
- This product could cause dizziness. If affected do not drive or operate machinery.

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 which may be severe such as skin rash, peeling of the skin, itching,

swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face

- 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.

Text revised: February 2016.

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