CONSUMER MEDICINE INFORMATION



PHARMACY ACTION COLD & FLU PSE

paracetamol, pseudoephedrine hydrochloride

What is in this leaflet

This leaflet answers some common questions about Pharmacy Action Cold & Flu PSE.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Pharmacy Action Cold & Flu PSE against the benefits they expected it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What Pharmacy Action Cold & Flu PSE is used for

This product is used for temporary relief of the following cold and flu symptoms: nasal congestion, sinus pain, runny nose, headache and body aches and pains. It also reduces fever.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Pseudoephedrine belongs to

a group of medicines called sympathomimetic decongestants. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Ask your pharmacist or doctor if you have any questions about this medicine. Your pharmacist or doctor may have given it for another reason.

This medicine is only available from a pharmacist.

Before you take/give Pharmacy Action Cold & Flu PSE

When you must not take it

Do not take Pharmacy Action Cold & Flu PSE if you have an allergy to:

- any medicine containing paracetamol or pseudoephedrine.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue, or other parts of the body;
- rash, itching or hives on the skin.

Do not take this medicine if you have:

very high blood pressure;

- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart);
- taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days.

Do not take this medicine if you are pregnant or plan to become pregnant. It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- liver or kidney disease:
- high blood pressure;
- overactive thyroid gland;

- diabetes:
- heart disease and poor blood flow in the blood vessels of the heart;
- glaucoma (high pressure in the eyes);
- prostate problems.

Ask your pharmacist or doctor about taking paracetamol and pseudoephedrine if you are breastfeeding.

Paracetamol may be used if you are breastfeeding. Small amounts of pseudoephedrine pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking Pharmacy Action Cold & Flu PSE.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Pharmacy Action Cold & Flu PSE may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots;
- metoclopramide, a medicine used to control nausea and vomiting;
- medicines used to treat epilepsy or fits;
- chloramphenicol, an antibiotic used to treat ear and eye infections;
- medicines used to treat

- depression:
- medicines used to treat heart conditions:
- medicines used to treat high blood pressure;
- medicines used to treat urinary tract infections and bladder problems;
- medicines used to treat behavioural disorders;
- phenylephrine, a medicine used to treat congestion;
- appetite suppressants;
- alcohol.

These medicines may be affected by Pharmacy Action Cold & Flu PSE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take Pharmacy Action Cold & Flu PSE

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your pharmacist or doctor for help.

How much to take

Adults and children 12 years and over: Take 2 tablets every 4 to 6 hours when necessary.

Do not give to children under 12 years.

Do not take more than the recommended dose.

No more than 4 doses

should be taken in 24 hours.

Pseudoephedrine may cause sleeplessness if it is taken up to several hours before going to bed.

Do not take with other products containing paracetamol unless advised to by a doctor or pharmacist.

How to take it

Take tablets as required with water.

When to take it

Take two (2) tablets every 4 to 6 hours when necessary.

How long to take it

Do not take this medicine for longer than a few days at a time (adults) or 48 hours at a time (children 12 years and over) unless advised to by a doctor.

If you forget to take it

If it is less than 2 to 3 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicines as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Pharmacy Action Cold & Flu PSE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Pharmacy Action Cold & Flu PSE

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Children 12 years and over:
Do not give this medicine
for more than 48 hours
unless a doctor has told you
to.

Do not give to children under 12 years.

Adults: Do not take for more than a few days at a time unless your doctor tells you to.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Do not take Pharmacy Action Cold & Flu PSE to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Only drink small quantities of alcohol (beer, wine or spirits) while taking this medicine. Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Be careful driving or operating machinery until you know how the medicine affects you. This medicine may cause dizziness in some people. If this happens, do not drive, use or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Pharmacy Action Cold & Flu PSE.

This medicine helps most people with temporary relief of the symptoms of cold and flu but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the

following list of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- nausea or dyspepsia;
- drowsiness:
- difficulty sleeping;
- nervousness;
- excitability;
- restlessness;
- dizziness:
- fear or anxiety;
- rapid heartbeat;
- tremors:
- hallucinations.

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

Children and people over 65 years of age may have an increased chance of getting side effects.

If any of the following happen, tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- urine retention;
- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and

when used for a short period of time.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Pharmacy Action Cold & Flu PSE

Storage

Keep your medicine in the original pack until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Pharmacy
Action Cold & Flu PSE or
any other medicine in the
bathroom or near a sink. Do
not leave it on a window sill
or in the car. Heat and
dampness can destroy some
medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

The tablets are white, round tablets with a break-line on one side.

This medicine is sold in a carton containing either 12 tablets in a blister pack or 24 tablets in 2 blister packs.

Ingredients

Pharmacy Action Cold & Flu PSE contains 500 mg of paracetamol and 30 mg of pseudoephedrine hydrochloride as the active ingredients.

It also contains:

- crospovidone;
- magnesium stearate;
- microcrystalline cellulose;
- povidone;
- pregelatinised maize starch:
- purified water;
- stearic acid.

Supplier

Pharmacy Action Cold & Flu PSE are supplied in Australia by:

Generic Health Pty Ltd Level 1, 1102 Toorak Road Camberwell, VIC 3124 Australia

AUST R 295160

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