

PANADOL® Cold & Flu Plus Decongestant

Paracetamol 500 mg and Phenylephrine Hydrochloride 5 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PANADOL Cold & Flu Plus Decongestant. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PANADOL Cold & Flu Plus Decongestant against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What PANADOL Cold & Flu Plus Decongestant is used for

PANADOL Cold & Flu Plus Decongestant caplets are used for the temporary relief of cold & flu symptoms including headache, body aches & pain, blocked or runny nose, sore throat. It also reduces fever.

PANADOL Cold & Flu Plus Decongestant contains the active ingredients paracetamol and phenylephrine hydrochloride.

Paracetamol works to stop the pain messages from getting through to the brain.

Phenylephrine hydrochloride works to reduce nasal stuffiness.

Ask your doctor or pharmacist if you have any questions about this medicine.

Your doctor or pharmacist may have given it for another reason.

This medicine is not addictive.

This medicine may cause dizziness. If affected, do not drive or operate machinery.

Before you take/give PANADOL Cold & Flu Plus Decongestant

Taking too much paracetamol can cause serious harm to your liver.

When you must not take it

Do not take PANADOL Cold & Flu Plus Decongestant if you have an allergy to:

- any medicine containing paracetamol or phenylephrine hydrochloride
- 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, throat or other parts of the body
- rash, peeling, itching or hives on the skin or mouth ulcers.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Always read and follow the label.

Do not take this medicine:

- If you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.**

- Within several hours of going to bed as it may cause sleeplessness.**
 - For more than 48 hours (in children 12-17 years) or more than a few days (adults), except on medical advice.**
 - If you are taking or have taken in the past 14 days, medicines called monoamine oxidase inhibitors (MAOIs) usually used to treat depression.**
 - If you are taking other medicines for the relief of colds & flu, congestion or blocked nose, appetite suppressants or stimulant drugs called amphetamines (sometimes used for attention deficit disorder).**
 - If you have very high blood pressure or severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart).**
- Medicines to treat depression such as MAOIs or tricyclic antidepressants
 - Medicines to treat anxiety or help you sleep
 - Other medicines for the relief of colds & flu, congestion or blocked nose, appetite suppressants or stimulants
 - Warfarin or similar medicines used to thin the blood
 - Medicines to control your blood pressure, such as beta-blockers
 - Digoxin or similar medicines for heart disease
 - Metoclopramide, a medicine used to control nausea and vomiting
 - Anticonvulsants, medicines used to treat epilepsy or fits
 - Chloramphenicol, an antibiotic used to treat ear and eye infections
 - Alcohol
 - Cholestyramine, a medicine used to lower cholesterol levels in the blood
 - Probenecid, a medicine used to treat gout
 - Medicines used to treat behavioural disorders

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 doctor.

Before you start to take it

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

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

- high blood pressure
- heart disease or
- blood vessel disease (e.g. Raynaud's phenomenon)
- diabetes
- overactive thyroid
- glaucoma
- phaeochromocytoma (a tumour near the kidney)
- prostate problems or difficulty urinating
- liver or kidney problems
- are underweight or malnourished
- regularly drink alcohol
You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- a severe infection as this may increase the risk of metabolic acidosis.
Sign of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetiteContact a doctor immediately if you get a combination of these symptoms.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking PANADOL Cold & Flu Plus Decongestant.

Taking other medicines

Tell your doctor or pharmacist 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 PANADOL Cold & Flu Plus Decongestant may interfere with each other. These include:

These medicines may be affected by PANADOL Cold & Flu Plus Decongestant 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take PANADOL Cold & Flu Plus Decongestant

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

Do not exceed the stated dose or frequency of dosing.

Always use the lowest effective dose to relieve your symptoms.

How much to take

Adults and children 12 years and over, take 2 caplets (capsule-shaped tablets) with water every 4 to 6 hours if required. Do not take more than 8 caplets in a 24 hour period. It does not matter if you take this medicine before or after food.

How long to take it

Adults:

Only take PANADOL Cold & Flu Plus Decongestant for a few days at a time except on medical advice.

Children aged 12 to 17 years:

Do not take for more than 48 hours except on medical advice.

Do not use in children below 12 years old.

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 PANADOL Cold & Flu Plus Decongestant. Seek medical advice immediately even if there are no signs of

discomfort or poisoning because of the risk of liver failure.

You may need urgent medical attention.

Taking too much paracetamol can lead to delayed, serious liver damage.

While you are using PANADOL Cold & Flu Plus Decongestant

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: Do not give to children under the age of 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 doctor tells you to.

Do not take PANADOL Cold & Flu Plus Decongestant to treat any other complaints unless your doctor tells you to.

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

Keep out of sight and reach of children.

Things to be careful of

Be careful driving or operating machinery until you know how PANADOL Cold & Flu Plus Decongestant affects you.

This medicine may cause drowsiness, dizziness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PANADOL Cold & Flu Plus Decongestant.

This medicine helps most people with the relief of sinus congestion and pain, nasal congestion or runny nose 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 lists of side effects. You may not experience any of them.

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

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

- Headache
- Dizziness
- Nervousness
- Difficulty sleeping
- Increased blood pressure
- Nausea
- Vomiting.

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

- If you experience allergic reactions such as:
 - skin rash or itching
 - breathing problems
 - swelling of the lips, tongue, throat or face
 - skin rash or peeling or mouth ulcers.

- If you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product.
- If you experience unexplained bruising or bleeding.
- If you experience an unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat.
- If you experience loss of vision, which may be due to abnormally high blood pressure in the eye. This is more likely to occur in those with glaucoma.
- If you experience difficulty in passing water. This is more likely to occur in men with enlarged prostate gland.

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

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

After using PANADOL Cold & Flu Plus Decongestant

Storage

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

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

Do not store PANADOL Cold & Flu Plus Decongestant 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PANADOL Cold & Flu Plus Decongestant is white capsule-shaped tablet (caplet) with flat edges, 17.7 mm x 7.1 mm, one face is embossed with the sun graphic within an oval.

Blister packs of 20 caplets.

Ingredients

PANADOL Cold & Flu Plus Decongestant contains 500 mg of paracetamol and 5 mg of phenylephrine hydrochloride as the active ingredients.

It also contains:

- Cellulose - microcrystalline
- Potassium sorbate
- Povidone
- Sodium lauryl sulphate
- Starch - maize
- Starch - pregelatinised maize
- Stearic acid
- Talc - purified.

Manufacturer/Distributor/Supplier

PANADOL Cold & Flu Plus Decongestant is supplied in Australia by:

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue, Ermington,
NSW

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