

Panadol® Cold & Flu Relief + Cough Caplets

Paracetamol 500mg, Dextromethorphan Hydrobromide 15mg, Phenylephrine Hydrochloride 5mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PANADOL COLD & FLU RELIEF + COUGH caplets.

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 PANADOL COLD & FLU RELIEF + COUGH caplets against the benefits they expect 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 PANADOL COLD & FLU RELIEF + COUGH CAPLETS are used for

PANADOL COLD & FLU RELIEF + COUGH CAPLETS are used for the temporary relief of the following symptoms of cold and flu: headache, runny or blocked nose, sore throat, dry cough, body aches and pains. Reduces fever.

PANADOL COLD & FLU RELIEF + COUGH caplets contain the active ingredients paracetamol, dextromethorphan hydrobromide and phenylephrine hydrochloride.

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

Dextromethorphan hydrobromide is a cough suppressant that is used to suppress a dry cough.

Phenylephrine HCl works to reduce nasal stuffiness.

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 not addictive.

It is only available in the pharmacy.

Before you take/give PANADOL COLD & FLU RELIEF + COUGH CAPLETS

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

When you must not take it

Do not take PANADOL COLD & FLU RELIEF + COUGH CAPLETS if you have an allergy to:

- any medicine containing paracetamol, dextromethorphan, or phenylephrine
- 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.

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
- if you have very high blood pressure, heart problems or are taking antidepressant medicines unless your doctor has told you to
- if you are taking or have taken in the last 14 days, drugs called monoamine oxidase inhibitors, medicines used to treat depression
- if you are taking other medicines for the relief of colds and flu, congestion or blocked nose, appetite suppressants or stimulant drugs called amphetamines (sometimes used for attention deficit disorder)
- if you are underweight or malnourished
- if you regularly drink alcohol You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- if you have a chest infection, worsening asthma or severe respiratory problems
- if you are having an asthma attack

- if you are pregnant or breastfeeding.

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 had any of the following medical conditions:

- liver or kidney disease
- overactive thyroid gland
- heart disease, blood vessel disease such as Raynaud's phenomenon (which may appear as pain in the fingers or toes in response to cold or stress)
- high blood pressure
- irregular heartbeat
- diabetes
- glaucoma (high pressure in the eyes)
- pheochromocytoma (a tumour near the kidney)
- prostate gland enlargements
- long term or persistent cough
- asthma, bronchitis or a chronic lung disorder or a cough with excessive phlegm
- 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 appetite.

Contact a doctor immediately if you get a combination of these symptoms.

Ask your pharmacist or doctor about taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS if you are pregnant or plan to become pregnant, or breastfeeding. 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 him/her before you start taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS.

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 PANADOL COLD & FLU RELIEF + COUGH CAPLETS may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots or similar medicines used to thin the blood
- metoclopramide, a medicine used to control nausea and vomiting
- phenytoin, a medicine used to treat epilepsy (fits)
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to treat depression (e.g. a selective serotonin reuptake inhibitor (SSRI) such as fluoxetine, or tricyclic antidepressant (such as amitriptyline, clomipramine or imipramine)
- monoamine oxidase inhibitors, a medicine used to treat depression, especially if taken within the last 14 days
- quinidine and amiodarone, medicines used to treat abnormal or irregular heartbeat

- opioid analgesics, medicines used to treat pain
- medicines to treat anxiety or help you sleep
- alcohol
- medicines used to treat:
 - heart conditions
 - high blood pressure
 - urinary tract infections and bladder problems
 - behavioural disorders
 - congestion.
- appetite suppressants.

These medicines may be affected by PANADOL COLD & FLU RELIEF + COUGH CAPLETS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take PANADOL COLD & FLU RELIEF + COUGH

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 box/bottle, ask your pharmacist or doctor 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). Do not take more than 8 caplets within 24 hours.

Do not take more than the recommended dose.

How to take

Take 2 caplets (capsule-shaped tablets) of PANADOL COLD & FLU RELIEF + COUGH CAPLETS by mouth with fluid as necessary.

When to take it

Adults and children 12 years and over:

Take 2 DAY caplets every 4-6 hours with water as necessary.

Maximum 8 caplets in 24 hours.

How long to take it

Adults and children 12 years and over:

Only take PANADOL COLD & FLU RELIEF + COUGH CAPLETS 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 RELIEF + COUGH CAPLETS. 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 RELIEF + COUGH

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve or if your cough is accompanied by high temperature, skin rash or persistent headache.

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 PANADOL COLD & FLU RELIEF + COUGH CAPLETS 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 RELIEF + COUGH CAPLETS 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.

Keep out of reach of children.

Do not drink alcohol while taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS.

The sedation effects of alcohol may be increased.

Things to be careful of

Avoid drinking alcohol (beer, wine or spirits) while taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS.

Drinking alcohol while taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS may increase the risk of side effects.

Be careful driving or operating machinery until you know how PANADOL COLD & FLU

RELIEF + COUGH CAPLETS affects you.

This medicine may cause drowsiness, dizziness or blurred vision in some people. You should not drive or operate machinery until you are sure you are not affected.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking PANADOL COLD & FLU RELIEF + COUGH CAPLETS.

This medicine helps most people with the relief of sinus congestion and pain, nasal congestion, runny nose or dry cough but there may be 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.

Children and the elderly are more likely to develop side effects with this medicine.

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, dyspepsia or vomiting
- drowsiness or sleepiness
- difficulty sleeping
- nervousness
- fatigue
- headache
- blurred vision
- excitability
- restlessness
- dizziness
- difficulty concentrating
- lack of co-ordination
- rapid heartbeat
- increased blood pressure
- dry mouth, nose and throat

- nervousness and irritability.

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:

- 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
- previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience similar reactions with this product
- difficulty passing water (this is most likely to occur in men with enlarged prostate gland)
- unexplained bruising or bleeding
- severe drowsiness or dizziness
- severe excitability
- unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat
- tremor
- hallucinations (this is rare but more likely in children)
- twitching or jerking muscles
- severe nausea and vomiting
- experience some or all of the following symptoms:
 - extreme confusion
 - nervousness and anxiety
 - restlessness
 - sweating
 - shaking
 - shivering
 - sudden jerks of the muscles
 - increased blood pressure.
 These may be symptoms of a condition called serotonin syndrome, which may be rare.
- loss of vision, which may be due to abnormally high blood pressure in the eye.
This is very rare but is more likely to occur in those with glaucoma.

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.

Please see your doctor if your symptoms do not improve, or if you develop a high temperature, skin rash or persistent headache.

After using PANADOL COLD & FLU RELIEF + COUGH CAPLETS

Storage

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

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

Do not store PANADOL COLD & FLU RELIEF + COUGH CAPLETS 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

PANADOL COLD & FLU RELIEF + COUGH CAPLETS are blue capsule-shaped tablet with flat edges. One face is marked with the sun within an oval.

A pack contains 24 caplets.

Ingredients

PANADOL COLD & FLU RELIEF + COUGH CAPLET contains 500mg paracetamol, 5mg Phenylephrine Hydrochloride and 15mg Dextromethorphan Hydrobromide as the active ingredients.

It also contains:

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

Manufacturer

PANADOL COLD & FLU RELIEF + COUGH CAPLETS is supplied in Australia and New Zealand by:

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue, Ermington, NSW and Auckland, New Zealand

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