

PLEASE READ CONSUMER MEDICINE INFORMATION BEFORE YOU START TO TAKE YOUR MEDICINE.

CONSUMER MEDICINE INFORMATION

Cold & Flu Tablets.

(Paracetamol, Codeine Phosphate, Pseudoephedrine Hydrochloride)

What is in this leaflet

This leaflet answers some common questions about Pharmacy Choice® Cold & Flu Tablets. 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 Choice® Cold & Flu Tablets 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 Pharmacy Choice® Cold & Flu Tablets is used for

This medicine is for the temporary relief of headache, body aches and pain associated with cold and flu, clears nasal congestion, dry runny nose, reduce fever and make breathing easier. 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 is used to relieve nasal congestion and dry runny noses. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, making it easier to breathe.

Codeine phosphate belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

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 your pharmacist.

Before you take/give Pharmacy Choice® Cold & Flu Tablets

When you must not take it

Do not take Pharmacy Choice® Cold & Flu Tablets if you have an allergy to:

- any medicine containing paracetamol, pseudoephedrine or codeine.
- 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 have or have had any of the following medical conditions:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

Do not take codeine if you have alcohol dependence.

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 codeine during labour, especially if the baby is premature. The medicine may produce withdrawal effects in the newborn baby.

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
- low blood pressure
- overactive thyroid gland
- underactive thyroid
- diabetes
- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)
- prostate problems
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- a history of drug dependence, including alcohol dependence
- recent surgery on the stomach or intestines
- head injury

Tell your pharmacist or doctor if you take sedatives (medicines used to help you relax or sleep).

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy, or breastfeeding.

Paracetamol may be used during pregnancy and if you are breastfeeding. However, small amounts of pseudoephedrine and codeine may pass into 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 him/her before you start taking Pharmacy Choice® Cold & Flu Tablets.

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 Choice® Cold & Flu Tablets 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
- alcohol
- 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
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- monoamine oxidase inhibitors, medicines used to treat depression, taken within the last 14 days
- other opioid analgesics used to treat pain
- quinidine, a medicine used to treat abnormal or irregular heart beat.
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders

These medicines may be affected by Pharmacy Choice® Cold & Flu Tablets 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 or doctor will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take Pharmacy Choice® Cold & Flu Tablets

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 over 12 years: one to two tablets every 4 to 6 hours as required with water. Do not exceed 8 tablets in 24 hours.
Not to be given to children under 12 years except under medical supervision.
Do not take more than the recommended dose.

Talk to your doctor about pain control if the medicine is not helping. If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine. If you are over 65 years of age, talk to your pharmacist or doctor about how much to take. Elderly patients are more likely to have less effective kidney function due to age. This may increase the risk of side effects.

How long to take it

Adults: Only take this product for a few days at a time unless your doctor tells you to take it for longer.
Children: Only give this product to children for up to 48 hours unless a doctor has told you to give it longer.

If you forget to take it

If it is less than 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 medicine 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 an unwanted side effect. 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 Choice® Cold & Flu Tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Pharmacy Choice® Cold & Flu Tablets

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 this product for more than 48 hours unless a doctor has told you to.

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 Pharmacy Choice® Cold & Flu Tablets 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 product. 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 Pharmacy Choice® Cold & Flu Tablets affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or use operate machinery.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Codeine may be habit forming.

Side effects

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

This medicine helps most people with temporary relief from headache, body ache and pain associated with cold and flu, clear nasal congestion, dry runny nose, as well as reducing fever and making breathing easier, 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 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 heart beat
- tremor
- hallucinations
- vomiting
- constipation

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.

Tell your doctor as soon as possible if you notice any of the following:

- shallow breathing or shortness of breath
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat

The above list includes serious side effects that may require medical attention. These side effects are rare. 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 Choice® Cold & Flu Tablets.

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 Pharmacy Choice® Cold & Flu Tablets 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

This medicine is sold in a carton with a blister pack containing 24 tablets.

Ingredients

Pharmacy Choice® Cold & Flu Tablets contains 500 mg of paracetamol, 30 mg of pseudoephedrine hydrochloride and 6 mg of codeine phosphate as the active ingredients.

It also contains: Cellulose microcrystalline, Crospovidone, Magnesium stearate, Pregelatinized starch, Povidone and Stearic Acid.

Distributed by:

Symbion Pharmacy Services Pty Ltd.

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TGA approved in November 2006.

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