

Codral Original Cold & Flu Tablets

Paracetamol, Pseudoephedrine hydrochloride, Codeine phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Codral Original 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 Codral Original Cold & Flu 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 Codral Original Cold & Flu is used for

Codral Original Cold & Flu tablets provide temporary relief from the symptoms of runny nose, nasal congestion, headache, body aches and pains and fever, without drowsiness.

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.

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 Codral Original Cold & Flu

When you must not take it

Do not take Codral Original Cold & Flu if you have an allergy to:

- * any medicine containing paracetamol
- * any medicine containing pseudoephedrine
- * any medicine containing 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 (EXP) 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 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:

- * low blood pressure
- * high blood pressure
- * underactive thyroid gland
- * 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
- * liver or kidney disease
- * 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).

Ask your pharmacist or doctor about taking Codral Original Cold & Flu if you are breastfeeding.

A small amount of this medicine passes 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 him/her before you start taking Codral Original Cold & Flu.

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 Codral Original Cold & Flu may interfere with each other.

These include:

- * warfarin, a medicine used to prevent blood clots
- * medicines used to treat heart conditions
- * medicines used to treat high blood pressure
- * quinidine, a medicine used to treat abnormal or irregular heart beat
- * metoclopramide, a medicine used to treat nausea and vomiting
- * medicines for diarrhoea, such as kaolin, pectin and loperamide
- * medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- * medicines used to treat urinary tract infections and bladder problems
- * medicines used to treat epilepsy or fits
- * medicines used to treat depression
- * medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- * monoamine oxidase inhibitors, medicines used to treat depression, taken within the last 14 days
- * phenothiazines and antipsychotic agents, medicines used to treat mental disorders.
- * medicines used to treat behavioural disorders
- * other opioid analgesics used to treat pain
- * chloramphenicol, an antibiotic used to treat ear and eye infections

- * phenylephrine, a medicine used to treat congestion
- * appetite suppressants
- * alcohol.

These medicines may be affected by Codral Original Cold & Flu 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 medicines to be careful with or avoid while taking this medicine.

How to take Codral Original Cold & Flu

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 pack, ask your pharmacist or doctor for help.

How much to take

The recommended dose of Codral Original Cold & Flu, for adults and children over 12 years, is 2 tablets 3 to 4 times a day.

Do not use this medicine for children under 12 years of age without medical advice.

Do not take more than the recommended dose.

If you are over 65 years of age, talk to you pharmacist or doctor about how much to take.

If you are over 65 years of age you may have an increased chance of getting side effects.

How to take it

Swallow tablets whole with a glass of water.

How long to take it

As Codral Original Cold & Flu contains paracetamol, take only for a few days at a time unless your doctor tells you to take it for longer.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, you may take a dose as soon as you remember if you think you need it.

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) 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 Codral Original Cold & Flu. Do this even if there are no signs of discomfort or poisoning.

While you are using Codral Original Cold & Flu

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

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

Do not take Codral Original Cold & Flu 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.

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

Things to be careful of

Only drink small quantities of alcohol while taking paracetamol.

Drinking large quantities of alcohol while taking this medicine may increase the risk of liver side effects.

Be careful driving or operating machinery until you know how Codral Original Cold & Flu affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or 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 Codral Original Cold & Flu.

This medicine helps most people with cold and flu symptoms, 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
- * vomiting
- * constipation
- * drowsiness
- * dizziness
- * difficulty sleeping
- * nervousness
- * excitability
- * restlessness
- * fear or anxiety
- * rapid heart beat
- * tremor
- * hallucinations.

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

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
- * 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.

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 Codral Original Cold & Flu

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 25 degrees C.

Do not store Codral Original Cold & Flu 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 your medicine 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

Codral Original Cold & Flu are round, white, bevelled, biconvex, uncoated tablets. They are scored and branded 'K7F' on the upper face and plain on the bottom face.

Codral Original Cold & Flu tablets are available in blister packs of 24 tablets.

Ingredients

Codral Original Cold & Flu tablets contain 500 mg of paracetamol, 30 mg of pseudoephedrine hydrochloride and 6 mg of codeine phosphate as the active ingredients. Codral Original Cold & Flu tablets also contain the following inactive ingredients:

- * microcrystalline cellulose
- * hydroxypropylcellulose
- * lactose
- * magnesium stearate
- * sodium starch glycollate
- * pregelatinised wheat starch
- * stearic acid.

This medicine does not contain sucrose, tartrazine or any other azo dyes.

Manufacturer

Codral Original Cold & Flu is made in Australia by:

Johnson & Johnson Pacific

45 Jones Street

Ultimo NSW 2007

CODRAL is a registered trademark.

This leaflet was prepared in August 2007.

Australian Register Number:

AUST R 51771