

Codral Original Day & Night Cold & Flu Tablets

Paracetamol, Pseudoephedrine hydrochloride, Codeine phosphate, Triprolidine hydrochloride

Consumer Medicine Information

What is in this leaflet

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

Codral Original Day & Night Cold & Flu tablets provide fast and effective temporary relief from the symptoms of colds and flu.

The DAY tablets relieve the symptoms of cold and flu during the day.

The NIGHT tablets relieve the symptoms of cold and flu, allowing restful sleep.

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.

Triprolidine belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine.

Histamine is produced by the body in response to foreign substances that the body is allergic to.

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 Day & Night Cold & Flu

When you must not take it

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

- any medicine containing paracetamol
- any medicine containing pseudoephedrine
- any medicine containing codeine
- any medicine containing triprolidine or other antihistamines
- 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).

Do not use this medicine if you are an ultra-rapid metaboliser of codeine.

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
- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems.

Do not take this medicine if you have alcohol dependence.

Do not take this medicine if you are also taking monoamine oxidase inhibitors (a type of medicine used to treat depression), or if you have taken monoamine oxidase inhibitors in the last 14 days.

Do not take this medicine during labour, especially if the baby is premature.

The medicine may produce withdrawal effects in the newborn baby.

Do not give this medicine to newborn or premature babies.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

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
- thyroid disease
- 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 (particularly if aged between 12 and 18 years)

- pulmonary oedema
- a history of drug dependence, including alcohol dependence
- recent surgery on the stomach or intestines
- obstructive bowel disorder
- head injury
- epilepsy.

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.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Codral Original Day & Night 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 Day & Night Cold & Flu may interfere with each other.

These include:

- warfarin, a medicine used to prevent blood clots
- medicines used to treat high blood pressure
- medicines used to treat heart conditions
- quinidine, a medicine used to treat abnormal or irregular heart beat
- metoclopramide, a medicine used to treat nausea and vomiting
- 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
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat epilepsy or fits
- medicines used to treat behavioural disorders
- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates, sedatives and hypnotics
- monoamine oxidase inhibitors, medicines used to treat depression, taken within the last 14 days
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- other opioid analgesics used to treat pain
- phenylephrine, a medicine used to treat congestion
- appetite suppressants

- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol.

These medicines may be affected by Codral Original Day & Night 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 Day & Night 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 doses of Codral Original Day & Night Cold & Flu, for adults and children 12 years and over, are:

- Day time: 2 white DAY tablets in the morning and again in the afternoon.
- Night time: 2 blue NIGHT tablets at bedtime.

Do not take more than the recommended dose.

Do not use this medicine in children under 12 years of age.

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

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 Day & Night Cold & Flu contains paracetamol, take only for a few days at a time in adults or for 48 hours in children 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 Day & Night Cold & Flu. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Codral Original Day & Night Cold & Flu

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve, worsen, or if new symptoms appear.

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.

Prolonged use of codeine may produce tolerance, and physical and psychological dependence.

Do not drink alcohol while taking Codral Original Day & Night Cold & Flu.

The sedative effects of alcohol may be increased.

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

Do not take Codral Original Day & Night 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

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

This medicine may cause drowsiness 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 Day & Night 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
- abdominal pain
- diarrhoea
- pain when passing urine
- vomiting
- constipation
- headache
- drowsiness or sleepiness
- dizziness

- difficulty sleeping
- nervousness and irritability
- excitability
- euphoria
- restlessness
- feeling jittery
- fear or anxiety
- dry mouth, nose and throat
- twitching or jerking muscles
- rapid or irregular 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 or shortness of breath
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat
- difficult or painful urination
- seizures (fits).

The above list includes serious side effects that may require medical attention. These side effects are rare.

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

- urine retention
- extreme sleepiness
- confusion
- shortness of breath
- shallow breathing
- 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 Day & Night 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°C.

Do not store Codral Original Day & Night 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 Day & Night Cold & Flu contain two types of tablets:

- DAY tablets which are round, white, bevelled, biconvex and uncoated. They are scored and branded 'K7F' on one face, and plain on the other face.
- NIGHT tablets which are turquoise, bevelled, capsule-shaped, flat and uncoated. They are scored on one face and coded 'S3F' each side of the score, and plain on the other face.
- Codral Original Day & Night Cold & Flu tablets are available in blister packs of 24 tablets.

Ingredients

The DAY tablets contain 500 mg paracetamol, 30 mg pseudoephedrine hydrochloride and 6 mg codeine phosphate as the active ingredients.

The DAY tablets also contain the following inactive ingredients:

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

The NIGHT tablets contains 500 mg paracetamol, 30 mg pseudoephedrine hydrochloride and 1.25 mg triprolidine hydrochloride as the active ingredients.

The NIGHT tablets also contain the following inactive ingredients:

- brilliant blue FCF
- microcrystalline cellulose
- hydroxypropylcellulose
- magnesium stearate
- povidone
- quinoline yellow.

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

Sponsor

Johnson & Johnson Pacific
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