

Codral Original Cold & Flu + Cough Day & Night Capsules

Paracetamol, Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide, Chlorpheniramine maleate

Consumer Medicine Information

What is in this leaflet

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

Codral Original Cold & Flu + Cough Day & Night provides temporary relief of cold and flu symptoms.

The DAY capsules give temporary relief of headache, body aches and pains, blocked nose, fever and dry irritated coughs, without causing drowsiness.

The NIGHT capsules give temporary relief of headache, body aches and pains, blocked nose, fever, dry irritated coughs and runny nose.

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.

Dextromethorphan is a cough suppressant that acts on the cough centre in the brain to suppress a dry cough.

Chlorpheniramine 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 Cold & Flu + Cough Day & Night

When you must not take it

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

- any medicine containing paracetamol
- any medicine containing pseudoephedrine
- any medicine containing dextromethorphan
- any medicine containing chlorpheniramine 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 are having an asthma attack.

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:

- 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 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 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 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
- 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
- asthma
- chronic obstructive airways disease
- pneumonia
- any other respiratory (breathing) conditions
- epilepsy.

Tell your pharmacist or doctor if you take sedatives.

Tell your pharmacist or doctor if you have a chronic cough.

This medicine may make your cough worse.

Tell your pharmacist or doctor if you have a condition that produces large amounts of mucus.

This medicine may make your condition worse.

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 + Cough Day & Night.

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 + Cough Day & Night 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 and amiodarone, medicines used to treat abnormal or irregular heart beat
- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to treat behavioural disorders

- medicines used to help you relax, sleep or relieve anxiety, such as sedatives and hypnotics
- medicines used to treat epilepsy or fits, including phenytoin
- opioid analgesics, medicines used to treat pain
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat urinary tract infections and bladder problems
- phenylephrine, a medicine used to treat congestion
- chloramphenicol, an antibiotic used to treat ear and eye infections
- appetite suppressants
- alcohol.

These medicines may be affected by Codral Original Cold & Flu + Cough Day & Night 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 will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take Codral Original Cold & Flu + Cough Day & Night

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 Cold & Flu + Cough Day & Night for adults and children over 12 years are:

- DAY dosage: one or two green 'Day' capsules in the morning, at

midday and in the afternoon, as required.

- NIGHT dosage: one or two red 'Night' capsules at bedtime, as required.

Codral Original Cold & Flu + Cough Day & Night is not recommended for children under 12 years of age.

Do not take more than the recommended dose.

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 capsules whole with a glass of water.

When to take it

Take each dose at least 4 to 6 hours apart.

Do not exceed four doses in 24 hours.

How long to take it

As Codral Original Cold & Flu + Cough Day & Night 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.

Your next dose should be taken in 4 to 6 hours if you think you need it.

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 (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 Codral Original Cold & Flu + Cough Day & Night. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

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 drink alcohol (beer, wine or spirits) while taking this medicine.

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 more than the recommended dose unless your doctor tells you to.

Do not take this medicine 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

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

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

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 + Cough Day & Night.

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
- stomach discomfort
- constipation
- drowsiness or sleepiness
- dizziness
- fatigue
- difficulty sleeping
- nervousness and irritability
- dry mouth, nose and throat
- excitability
- restlessness
- fear or anxiety
- rapid heart beat
- tremor
- twitching or jerking muscles

- 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:

- muscle spasms affecting the eyes, head, neck and body
- 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, tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- urine retention
- excitation
- extreme confusion
- nervousness and anxiety
- irritability
- restlessness
- severe nausea and vomiting
- 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 Codral Original Cold & Flu + Cough Day & Night

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 + Cough Day & Night 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 + Cough Day & Night contain two types of capsules:

- DAY capsules which are blue green/white opaque hard gelatin capsules with 'Day' printed in black.
- NIGHT capsules which are reddish orange/white opaque hard gelatin capsules with 'Nighting' printed in black.

Codral Original Cold & Flu + Cough Day & Night capsules are available in blister packs of 24 capsules (18 DAY capsules and 6 NIGHT capsules).

Ingredients

The DAY capsules contain 500 mg of paracetamol, 30 mg of pseudoephedrine hydrochloride and 10 mg of dextromethorphan hydrobromide as the active ingredients.

The DAY capsules also contain the following inactive ingredients:

- allura red AC
- brilliant blue FCF
- gelatin
- lactose
- magnesium stearate
- quinoline yellow
- anhydrous colloidal silica
- silicon dioxide
- sodium lauryl sulfate
- purified talc
- titanium dioxide
- Opacode Black A-10259.

The NIGHT capsules contain 500 mg of paracetamol, 2 mg of chlorpheniramine maleate and 10 mg of dextromethorphan hydrobromide as the active ingredients.

The NIGHT capsules also contain the following inactive ingredients:

- allura red AC
- brilliant blue FCF
- gelatin
- lactose
- magnesium stearate
- anhydrous colloidal silica
- silicon dioxide
- sodium lauryl sulfate
- purified talc
- titanium dioxide
- Opacode Black A-10259.

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

Manufacturer

Codral Original Cold & Flu + Cough Day & Night is made in Australia by:

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007

CODRAL is a registered trademark.

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