CODRAL Original Day & Night + Dry Cough

Active ingredient(s): *Paracetamol and Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide monohydrate and Chlorphenamine maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CODRAL Original Day & Night + Dry Cough. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CODRAL Original Day & Night + Dry Cough.**

Where to find information in this leaflet:

1. Why am I using CODRAL Original Day & Night + Dry Cough?
2. What should I know before I use CODRAL Original Day & Night + Dry Cough?
3. What if I am taking other medicines?
4. How do I use CODRAL Original Day & Night + Dry Cough?
5. What should I know while using CODRAL Original Day & Night + Dry Cough?
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1. Why am I using CODRAL Original Day & Night + Dry Cough?

CODRAL Original Day & Night + Dry Cough contains the active ingredients Paracetamol and Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide monohydrate and Chlorphenamine maleate. Paracetamol is an analgesic. It works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever. Pseudoephedrine hydrochloride 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. Chlorphenamine 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.

CODRAL Original Day & Night + Dry Cough is used for the temporary relief from the symptoms of cold and flu. 'Day' capsules temporarily relieve headaches, body aches and pains, blocked nose, fever and dry irritated coughs without causing drowsiness. 'Night' capsules temporarily relieve headaches, body aches and pains, blocked nose, fever and dry irritated coughs and a runny nose.

2. What should I know before I use CODRAL Original Day & Night + Dry Cough?

Warnings

Do not use CODRAL Original Day & Night + Dry Cough if:

- you are allergic to Paracetamol, Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide monohydrate, Chlorphenamine maleate or other antihistamines, or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.
- you are younger than 12 years
- have very high blood pressure or high blood pressure not controlled by your medication
- have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- have severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- have taken other products containing paracetamol
- have taken antihistamines
- have taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days.

Check with your doctor or pharmacist if you:

- have any other medical conditions
  - respiratory conditions (such as asthma, chronic obstructive airway disease, chronic cough, excessive secretions or pneumonia)
  - 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
  - bladder problems
  - liver or kidney disease
  - alcohol dependence
  - epilepsy
- take sedatives
- take any medicines for any other condition
- have severe illnesses, including blood infection, are severely malnourished or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis (a blood and fluid abnormality). Signs of metabolic acidosis include:

- deep rapid, difficult breathing
- drowsiness
- feeling sick (nausea) being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you think you may be affected.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Small amounts of pseudoephedrine pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CODRAL Original Day & Night + Dry Cough and affect how it works.

These include

- medicines used to treat depression especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to treat heart conditions
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- quinidine and amiodarone, medicines used to treat abnormal or irregular heart beat
- medicines used to treat behavioral disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants
- 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 help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain flucloxacillin(an antibiotic) due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CODRAL Original Day & Night + Dry Cough.

4. How do I use CODRAL Original Day & Night + Dry Cough?

How much to take

- The recommended dose of CODRAL Day & Night + Dry Cough for adults and children over 12 years is

  Day time: 2 Day capsules every 4-6 hours

  Night time: 2 Night capsules at night time as necessary
- Follow the instructions provided with the medicine.
- Do not exceed 6 day capsules and 2 night capsules in 24 hours.
- Do not exceed the recommended dosage.

When to take CODRAL Original Day & Night + Dry Cough

- Day capsules should be used every 4 to 6 hours as necessary.
- Night capsules should be taken at night time as necessary.

How to take CODRAL Original Day & Night + Dry Cough

- Swallow the tablets whole.
- Do not use for more than a few days at a time except on medical advice.
- Follow all directions given to you by your pharmacist or doctor carefully. This may differ from the information contained in this leaflet.
- If you forget to take it and 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.
- If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

If you use too much CODRAL Original Day & Night + Dry Cough

If you think that you have used too much CODRAL Original Day & Night + Dry Cough, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CODRAL Original Day & Night + Dry Cough?

Things you should do

Stop use and talk to your doctor or pharmacist if your symptoms persist, worsen, or if new symptoms occur. Your doctor or pharmacist will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using CODRAL Original Day & Night + Dry Cough.

Things you should not do

- Do not take CODRAL Original Day & Night + Dry Cough 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CODRAL Original Day & Night + Dry Cough affects you.

CODRAL Original Day & Night + Dry Cough may cause dizziness in some people.

If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol while taking CODRAL Original Day & Night + Dry Cough. The sedative effects of alcohol may be increased.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
• dyspepsia • stomach discomfort • diarrhoea • constipation • drowsiness or sleepiness • dizziness • insomnia • difficulty sleeping • nervousness and irritability • fatigue • excitability • restlessness • fear or anxiety • twitching or jerking muscles • dry mouth, nose and throat • rapid or irregular heart beat • tremor • headache • hallucinations • rectal bleeding • small bumps on the skin with or without fever or reddening of the skin	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• urine retention • pain when passing urine • muscle spasms affecting the eyes, head, neck and body • seizures (fits) • confusion • 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 • severe headache with sudden onset • changes in vision Signs of metabolic acidosis which include: • deep, rapid, difficult breathing • feeling sick (nausea), being sick (vomiting) • loss of appetite • drowsiness	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Children and people over 65 years if age may have an increased chance of getting side effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What CODRAL Original Day & Night + Dry Cough contains

Day Capsules

Active ingredient (main ingredient)	Paracetamol Pseudoephedrine hydrochloride Dextromethorphan hydrobromide monohydrate
Other ingredients	Allura Red AC Brilliant blue FCF
(inactive ingredients)	Carbon black Ethanol Gelatin Lactose monohydrate Magnesium stearate Pharmaceutical glaze Purified talc Quinoline yellow Shellac Silicon dioxide Sodium lauryl sulfate Titanium dioxide

Night Capsules

Active ingredient (main ingredient)	Paracetamol Dextromethorphan hydrobromide monohydrate Chlorphenamine maleate
Other ingredients (inactive ingredients)	Allura Red AC Brilliant blue FCF Carbon black Ethanol Gelatin Lactose monohydrate Magnesium stearate Pharmaceutical glaze Purified talc Shellac Silicon dioxide Sodium lauryl sulfate Titanium dioxide

Do not take this medicine if you are allergic to any of these ingredients.

What CODRAL Original Day & Night + Dry Cough looks like

Day capsules are blue green/white opaque hard gelatin capsules, printed "Day" in black.

Night capsules are reddish orange/white opaque hard gelatin capsules, printed "Night" in black.

(Aust R 73421).

Who distributes CODRAL Original Day & Night + Dry Cough

Kenvue Pacific

Australia New Zealand

Sydney, NSW, Australia and Auckland New Zealand

Phone: 1800 029979

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