

Package leaflet: Information for the user
Co-codamol 8mg/500mg Tablets
codeine phosphate and paracetamol

This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **This medicine is available only on prescription.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Co-codamol Tablets are and what they are used for
2. What you need to know before you take Co-codamol Tablets
3. How to take Co-codamol Tablets
4. Possible side effects
5. How to store Co-codamol Tablets
6. Contents of the pack and other information

1. What Co-codamol Tablets are and what they are used for

The name of your medicine is Co-codamol 8mg/500mg Tablets. The active ingredients in Co-codamol are paracetamol and codeine phosphate. This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

Codeine can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone. For the symptomatic relief of pain including headache, migraine, toothache, period pains, rheumatic pains, including muscle pains and backache.

2. What you need to know before you take Co-codamol Tablets

Do not take for longer than directed by your prescriber

This medicine contains codeine which can cause **addiction** if you take it continuously for more than three days. This can give you **withdrawal** symptoms from the medicine when you stop taking it.

If you take a painkiller for headaches for more than three days it can make them worse.

Do not take Co-codamol if:

- You are allergic (hypersensitive) to paracetamol, codeine, other opioid analgesics or any of the other ingredients of this medicine (listed in section 6). Refer to section 4 (possible side effects) for the signs and symptoms of an allergic reaction.

- You drink excessive amounts of alcohol.
- You have severe problems with breathing.
- You have recently had a head injury or have increased pressure within your head (raised intracranial pressure).
- You are having an asthma attack
- You are under 12 years of age.
- You are at risk from intestinal paralysis or have a swollen abdomen.
- You are suffering from severe diarrhoea (pseudomembranous colitis).
- You are taking any other paracetamol or paracetamol-containing products.
- You are under 18 years of age and suffer from pain after removal of tonsils or adenoids due to obstructive sleep apnoea syndrome.
- You know that you metabolise very rapidly codeine into morphine
- You are breastfeeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-codamol if:

- You are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression
- You are pregnant or breast-feeding (see '**Pregnancy, breast-feeding**' below).
- You have asthma, bronchitis or emphysema. If your asthma is controlled you can take co-codamol tablets, but use with care, especially if your asthma is known to be made worse by aspirin or other painkillers. You should not take codeine if you are having an acute asthma attack.
- You have serious problems with your liver or kidneys.
- You have an under active thyroid (hypothyroidism) or adrenal glands.
- You have an enlarged prostate (men) or have difficulty passing water.
- Your alcohol consumption is excessive.
- You suffer from low blood pressure, are in a state of severe shock or very run down.
- You are elderly
- You have inflammation of the bowel or a blockage of the bowel
- You suffer from myasthenia gravis (a disease characterised by weakness of certain groups of muscles)
- You suffer from biliary tract disorders such as gallstones
- You are a poor metaboliser of codeine
- You suffer from convulsions or have a seizure disorder (fits).
- You have had a drug addiction.

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Co-codamol Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets. Your prescriber

should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else.

Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

This product contains paracetamol. Do not take with any other paracetamol containing products.

If you go into hospital for surgery or tests, tell your doctor you are taking co-codamol tablets, as they may interact with some anaesthetics and influence the results of certain tests and diagnostic procedures.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Talk to your doctor or pharmacist before taking opioids. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

During treatment with Co-codamol, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Co-codamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you have bought yourself without a prescription.

In particular you should tell your doctor if you are taking any of the following:

- Paracetamol or paracetamol-containing products
- Barbiturates (to help you sleep or treat epilepsy)
- Anticonvulsants such as carbamazepine, phenobarbital, phenytoin and primidone (drugs used to treat epilepsy)
- Antidepressants (tricyclics or MAOIs)
- Antipsychotics such as chlorpromazine and haloperidol (used to treat mental illnesses including schizophrenia)
- Anxiolytics (to help with anxiety)
- Hypnotics e.g. diazepam and nitrazepam (to help you sleep)
- Anaesthetics, particularly general anaesthetics (used in surgery to numb pain)
- Antihistamines such as benadryl (used to treat allergies e.g. hayfever)
- Sodium oxybate (used to treat narcolepsy)
- Sedatives (to help you relax)
- Colestyramine (used to lower cholesterol)
- Cisapride, metoclopramide or domperidone (used to help stop nausea and vomiting)
- Anticoagulants (medicines used to thin the blood, such as warfarin)
- Cimetidine (for stomach ulcers)
- Quinidine, mexiletine (used to regularise heart rhythm)
- Isoniazid (used to treat tuberculosis)
- Diflunisal (a painkiller)
- Oral contraceptives
- Probenecid (used to treat gout)
- Antidiarrhoeals such as loperamide or kaolin
- Medicines which affect the liver (e.g. primidone and rifampicin)
- Muscle relaxants
- Opioid antagonists (buprenorphine, naltrexone, naloxone)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment.

Concomitant use of Co-codamol 8mg/500mg Tablets and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Co-codamol 8mg/500mg Tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Co-codamol with food, drink and alcohol

Do not drink alcohol while you are taking Co-codamol. Alcohol may increase the sedative effects of Co-codamol and make you very sleepy. It can also increase the risk of some side effects.

Pregnancy and breast-feeding

Pregnancy

Do not take Co-codamol 8mg/500mg Tablets during pregnancy, unless advised by your doctor. Regular use during pregnancy may cause withdrawal symptoms in the newborn.

Breastfeeding

Do not take Co-codamol 8mg/500mg Tablets while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Codeine may cause drowsiness and/or blurred or double vision in some people. Do not drive or use any tools or machines if you are affected in this way and do not drink alcohol, as this will make these effects worse. Other medicines may also increase these effects.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Co-codamol Tablets contain parahydroxybenzoates

This medicine contains ethylhydroxybenzoate, methylhydroxybenzoate and propylhydroxybenzoate all of which may cause allergic reactions (possibly delayed).

3. How to take Co-codamol Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is described below. These tablets are for oral administration. They should be swallowed with a glass of water.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Dosage instructions

Adults: One to two tablets every 4 to 6 hours as required to a maximum of 8 tablets in 24 hours.

Elderly: Your doctor may have reduced the dose for you. If this is the case follow your doctor's instructions.

You may need a reduced dose if your kidney or liver is not working as well as it should be. You may also be given a reduced dose if you suffer from any of the conditions listed above in the section headed 'Talk to your doctor or pharmacist before taking Co-codamol if'.

Children 16 – 18 years: One to two tablets every 6 hours as required to a maximum of 8 tablets in 24 hours.

Children 12 - 15 years: One tablet every 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Children under 12 years: Co-codamol tablets should not be taken by children below the age of 12 years due to the risk of severe breathing problems.

Do not take more tablets than your doctor has prescribed for you.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

If you take more Co-codamol than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take Co-codamol

Take your usual dose as soon as you remember, provided it is at least 4 hours (6 hours if a child aged between 12 to 18 years) since your last dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-codamol

This medicine contains codeine which can cause **addiction** if you take it continuously for more than three days. When you stop taking it you may get **withdrawal** symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is very unlikely that you will experience the following side effects. However, you should **stop** taking this medicine and talk to your doctor **immediately** if you notice any of the following symptoms:

Uncommon: may affect up to 1 in 100 people

- **Urinary system** – kidney problems.
- **Drug withdrawal**
When you stop taking co-codamol 8mg/500mg Tablets, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

Rare: may affect up to 1 in 1,000 people

- **Allergic Reactions** – skin or itchy skin, mucosal lesions (such as mouth ulcers), drug fever

Not known: frequency cannot be estimated from the available data

- **Allergic Reactions** - difficulty breathing, increased sweating, redness or flushed face
- **Gastrointestinal system** - stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, feeling or being sick, loss of appetite, dry mouth, difficulty in the passage of food through guts, abdominal pain (may be caused by spasm of the bile ducts) and inflammation of the liver or pancreas
- **Heart** - slow heart rate, palpitations, low blood pressure, inflammation of the heart muscle
- **Blood** - anaemia, changes in numbers and types of blood cells. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor, a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)
- **Immune system** – anaphylactic shock, angioedema
- **Urinary system** - pain and difficulty in passing urine and a less frequent need to do so
- **Nervous system** - confusion, drowsiness, dizziness, ‘spinning’ sensation, mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, difficulty sleeping, nightmares, reduced alertness, tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, difficulty sleeping, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)
- **Eyes** - blurred or double vision, extremely small pupils
- **Others** - trembling, unusual tiredness or weakness, malaise, low body temperature
- dependence and addiction (see section “How do I know if I am addicted?”).

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

How do I know if I am addicted?

If you take this medicine as prescribed, it is unlikely that you will become addicted to the medicine. If you notice any of the following signs whilst taking Co-codamol 8/500mg Tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better if you start taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-codamol Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package or container in order to protect from light and moisture.

Never transfer medicines from one container to another.

Never take medicines from an unlabelled container.

This medicine is for you. Never offer your tablets to other people, even if their symptoms seem the same as yours, the tablets may not be suitable for their use.

This medicine is for you. Never offer your tablets to other people, even if their symptoms seem the same as yours. The tablets may not be suitable for their use.

Do not throw away any medicines via wastewater or household waste. Ask your prescriber how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-codamol contains

The active substances are paracetamol, 500mg and codeine phosphate, 8mg.

The other ingredients are maize and potato starch, povidone, stearic acid, talc, magnesium stearate, methyl-p-hydroxy benzoate (E218), ethyl-p-hydroxy benzoate (E214) and propyl-p-hydroxy benzoate (E216).

What Co-codamol looks like and contents of the pack

Co-codamol Tablets are white round tablets.
Packs of 48, 50, 96 and 100 tablets are only available on prescription from a doctor. Packs of 250, 500 and 1000 tablets are dispensary packs only.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Co-codamol 8mg/500mg Tablets	29831/0432

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