

Package leaflet: Information for the user

Co-codamol 30mg/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 because it contains important information for you.

- 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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

This medicine has been prescribed to you to relieve severe pain such as muscular and rheumatic pain, headache, migraine, neuralgia toothache and period pains. It contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. 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.

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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-CODAMOL TABLETS

Do not take Co-codamol Tablets if:

- You are allergic (hypersensitive) to paracetamol, codeine, any other opioid analgesic or any of the other ingredients in Co-codamol Tablets.
- You drink excessive amounts of alcohol.
- You have severe asthma, bronchitis, breathing problems or if you are having an asthma attack.
- You have recently had a head injury or have increased pressure within your head (raised intracranial pressure).
- You are under 12 years of age.
- You are suffering from severe diarrhoea.
- You have been told you have liver disease.
- You are at risk of a blocked intestine.
- You are in a coma.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- If you know that you metabolise very rapidly codeine into morphine
- If you are breast-feeding

Take special care with Co-codamol Tablets

Before taking this medicine, you need to know the following:

- This product contains paracetamol. Do not take with any other paracetamol containing products.
- If your symptoms last for more than 3 days talk to your doctor.

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

- You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below).
- 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 have asthma, bronchitis or emphysema. You should not take codeine if you are having an acute asthma attack.
- You have serious problems with your liver or kidneys.
- You are elderly, as you may need a lower dose.
- You are being treated with depressants (medicines used to treat anxiety).
- You have an enlarged prostate.
- You have an inflamed bowel or obstructive bowel disorder.
- You have an under active thyroid.
- You suffer from biliary tract disorders such as gallstones.
- You are very run down.
- You suffer from convulsions (fits).
- You are a poor metaboliser of codeine.
- You have had a drug addiction.
- You have Addison's disease.
- You have a poorly functioning adrenal gland.
- You have difficulty passing water.
- You have low blood pressure or shock.
- You have weak muscles (myasthenia gravis).

Warnings and precautions

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.

Caution should be exercised when taking paracetamol prior to (less than 72 hours before) or at the same time as intravenous busulfan.

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. 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.

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.

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.

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 Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken 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:

- Antidepressants such as phenelzine, dosulepin (Tricyclic and MAOIs), chlorpromazine (phenothiazines).
- Anxiolytics (to help with anxiety).
- Antipsychotics (to help mood disorders).
- Hypnotics such as diazepam, nitrazepam and temazepam (to help you sleep).
- Cholestyramine (used to lower cholesterol).
- Cisapride, metoclopramide or domperidone (used to help stop nausea and vomiting).
- 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).
- Anticoagulants (medicines used to thin the blood, such as warfarin).
- Antidiarrhoeal agents such as loperamide or kaolin.
- Muscle relaxants such as atropine.
- Cimetidine (used to treat stomach ulcers and indigestion).
- Anti-arrhythmic agents such as flecainide, quinidine and mexiletine.
- Intravenous busulfan (used in chemotherapy to treat cancer).

Co-codamol Tablets with food and drink and alcohol

Do not drink alcohol while you are taking Co-codamol Tablets. 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

Do not take Co-codamol Tablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Co-codamol Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Co-codamol Tablets while you are breastfeeding as codeine passes into breast milk and will affect your baby.

Driving and using machines

Codeine may cause drowsiness or changes in vision, including 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.

3. HOW TO TAKE CO-CODAMOL TABLETS

Always take Co-codamol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is described below.

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.

These tablets are for oral administration. They should be swallowed with a glass of water.

Dosage instructions

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

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: Not recommended for children under 12 years due to the risk of severe breathing problems.

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

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

The dose should be reduced in patients with liver problems.

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 Tablets than you should

Always take the medicine as recommended by your doctor. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take Co-codamol Tablets

Take your usual dose as soon as you remember, provided it is at least 4 hours (6 hours if a child aged between 12 and 18 years) since your last dose. Never take a double dose to make up for a missed dose.

If you stop taking Co-codamol Tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, co-codamol can cause side effects, although not everybody gets them. Tell your doctor if you think your medicine is making you feel unwell.

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:

- You have an allergic reaction. The signs of an allergic reaction may include: a rash, wheals or itching, difficulty breathing or swallowing, swelling of your lips, face, throat or tongue.

Other side effects that some people notice when taking Co-codamol Tablets are listed below:

- Constipation
- Nausea (feeling sick)
- Vertigo (a feeling of dizziness or 'spinning')
- Dizziness
- Drowsiness
- Confusion
- Vomiting (being sick)
- Pain or difficulty in passing urine
- Dry mouth
- Sweating
- Facial flushing
- Slower or faster heart rate
- Palpitations (feeling your heartbeat)
- Feeling faint on standing up
- Low body temperature
- Difficulty breathing
- Stomach cramps
- Increased or decreased frequency of passing urine
- Restlessness
- Mood changes including depression, sadness and euphoria
- Hallucinations (seeing or hearing things that are not there)
- Nightmares
- Pinpoint pupils
- Blurred vision
- Double vision or other changes in vision

- Pressure on the brain
- Kidney damage
- Blood disorders (such as thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising), neutropenia and leucopenia (reduction in white blood cells, which may make infection more likely) and pancytopenia (severe reduction in blood cells which can cause weakness, bruising or make infections more likely)
- Sore throat or ulcers in the mouth or throat
- Low sex drive
- Hyperglycaemia (abnormally high levels of glucose in the blood)
- Pancreatitis (inflammation of the pancreas)
- Feeling tired
- Feeling unwell
- Hypothermia
- Biliary spasms (causing a pain in the right side of your abdomen, particularly after eating a meal)
- Fever
- Enlarged spleen or swollen/enlarged lymph nodes
- Anorexia
- Uncontrolled muscle movements
- Muscle rigidity
- Weak erection in men
- Headaches made worse by taking co-codamol tablets
- Very rare cases of serious skin reactions have been reported.
- 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.

Drug Withdrawal

When you stop taking Co-codamol 30/500mg 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Co-codamol 30/500mg 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 feel 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 once 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 inner container or if the tablets show signs of 'going off' such as discoloration.

The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container.

Remember this medicine is for **you** only. **Never** give it to anyone else. It may harm them, even if their symptoms are the same as yours. Unless your doctor tells you to, do not keep tablets that you no longer need. Give them back to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-codamol Tablets contain

The active ingredients in Co-codamol Tablets are paracetamol, 500mg and codeine phosphate, 30mg.

The other ingredients are pregelatinised maize starch, magnesium stearate and povidone K30.

What Co-codamol Tablets look like and contents of the pack

Co-codamol Tablets are white, circular tablets marked CCD 30 on one face and CP on the reverse.

They are available in packs of 28, 30, 56, 60, 84, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

CP Pharmaceuticals Limited, 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 30mg/500mg Tablets	29831/0047

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 **WOCKHARDT**