

Package leaflet: Information for the user
Co-codamol 30mg/500mg effervescent tablets
Codeine phosphate/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.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your 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 30/500 is and what it is used for
2. What you need to know before you take Co-codamol 30/500
3. How to take Co-codamol 30/500
4. Possible side-effects
5. How to store Co-codamol 30/500
6. Contents of the pack and other information

1. What co-codamol 30/500 is and what it is used for

The name of this medicine is Co-codamol 30mg/500mg Effervescent Tablets, which will be referred to as Co-codamol 30/500 throughout this leaflet.

This medicine has been prescribed for you for the relief of severe 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.

Co-codamol 30/500 contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. It also contains paracetamol, another analgesic to relieve pain. 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.

2. What you need to know before you take co-codamol 30/500

Important things you should know about Co-codamol 30/500

Do not take for longer than your doctor tells you to.

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.

Taking a painkiller for headaches too often or for too long can make them worse

Do not take Co-codamol 30/500 if you:

- are **allergic** (hypersensitive) to codeine, **paracetamol** or any of the **other ingredients** in your medicine (listed in section 6). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face throat or tongue.
- have severe asthma attacks or severe breathing problems
- have recently had a head injury
- have been told by doctor that you have increased pressure in your head. Signs of this include: headache, being sick (vomiting) and blurred eyesight
- have recently had an operation on your liver, gall bladder or bile duct (biliary tract)
- are taking medicine to treat depression or called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks, MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine (see "Other medicines and Co-codamol 30/500")
- are an alcoholic
- the person going to take the tablets is under 12 years of age.
- are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- know that you metabolise very rapidly codeine into morphine
- are breastfeeding

Do not take Co-codamol 30/500 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-codamol 30/500.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-codamol 30/500

- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more of Co-codamol 30/500 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.
- if you have severe liver or kidney problems.
- if you have problem passing water or prostate problems.
- if you have bowel problems such as colitis or Crohn's disease or a blockage of your bowel.
- if you are elderly
- if you are sensitive to aspirin or other medicines used for the treatment of inflammation (Non-Steroidal Anti-inflammatory Drugs) such as Ibuprofen.
- If you are taking a benzodiazepine.
- If you know you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable to you.

- If you are taking a medicine that induces CYP3A4 enzyme activity such as rifampicin.
- If you have a condition called myasthenia gravis which weakens the muscles.

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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Co-codamol 30/500 can affect the way some other medicines work. Also, some other medicines can affect the way Co-codamol 30/500 works.

Other medicines and Co-codamol 30/500

Concomitant use of Co-codamol 30/500 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 30/500 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.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking or have taken within the last two weeks:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression
- medicines which make you drowsy or sleepy (CNS depressants and benzodiazepine) such as medicines used to treat anxiety or anaesthetics.
- medicines for depression such as dosulepin, mirtazapine (Tricyclic) or chlorpromazine (phenothiazines).
- medicines known as tranquillisers, or hypnotics
- sleeping tablets, sedatives and some antihistamines

You may experience more drowsiness if you take these medicines with co-codamol.

Tell your doctor or pharmacist if you are taking any other medicines:

- Medicines used to thin the blood such as warfarin.
- Chloramphenicol - an antibiotic used for infections
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine - for lowering blood cholesterol levels.
- The oral contraceptive pill
- Medicines such as quinidine, fluoxetine, paroxetine, bupropion, cinacalcet, methadone or rifampicin, as these may alter the effect of Co-codamol 30/500.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-codamol 30/500.

Co-codamol with food, drink and alcohol

You should not drink alcohol while you are taking these tablets. This is because co-codamol can change the way alcohol affects you.

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.

Pregnancy and breast-feeding

Do not take Co-codamol 30/500 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 30/500 during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

Driving and using machines

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 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 30/500 contains sodium and aspartame.

This medicine contains 438 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 21.9% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 5 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Changing or stopping treatment

Long term usage of Co-codamol 30/500 may lead to tolerance and dependence. If you have taken regular daily doses of Co-codamol 30/500 for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

3. How to take co-codamol 30/500

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure

- **Do not take more than the recommended dose.** If painful symptoms are not relieved in a few days, consult your doctor.
- Do not take for longer than your doctor tells you to
- Elderly people may be prescribed a lower dose

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.

The recommended dose is:

Adults: 2 tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 16 to 18 years: 1 to 2 tablets every 6 hours when necessary up to a maximum of eight doses in 24 hours.

Children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of four doses in 24 hours.

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.

Use in children

Co-codamol should not be given to children under 12 years of age due to the risk of severe breathing problems.

Method of Administration

For oral administration only. These tablets should be dissolved in at least half a glass of water before taking them. The solution should be drunk immediately after preparation. These tablets are meant to be dissolved first so don't try to swallow them whole.

Strip has sharp edges that may cause injury to hands. Take care when opening/tearing the strip.

If you take more Co-codamol 30/500 than you should:

If you have accidentally taken more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken.

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 30/500:

If you forget to take one or more doses, take your next dose when you remember and then go on as prescribed. Do not take a double dose to make up for a forgotten dose. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 4 hours between doses.

If you stop taking Co-codamol 30/500

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 about this medicine, ask your doctor or pharmacist.

4. Possible side-effects

As with all medicines, Co-codamol 30/500 can cause side-effects although not everybody gets them.

The following side effects may happen with this medicine:

Important side effects you should know about Co-codamol 30/500

- Taking a painkiller for headache too often or for too long can make them worse.
 - Unknown frequency: dependence and addiction (see section “How do I know if I am addicted?”).

Stop taking Co-codamol 30/500 and see a doctor or get to a hospital straight away:

- You have difficulty in breathing or you feel dizzy.
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having **an allergic reaction** to Co-codamol 30/500.
- You get serious skin reactions. Very rare cases of serious skin reactions have been reported.

Talk to your doctor straight away if you notice the following serious side effect

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Constipation
- Feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, fainting, drowsiness, confusion
- Difficulty in passing water (urine)
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)

- Difficulty breathing, wheezing, tightness in the chest (bronchospasm)

Drug Withdrawal

When you stop taking Co-codamol 30/500, 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 30/500, 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: <https://yellowcard.mhra.gov.uk/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 30/500

Do not store your tablets above 25°C. Store in a dry place and protect from light.

Do not take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish.

Store your medicine in the original packaging in order to protect from moisture.

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

6. Contents of the pack and other information

What Co-codamol 30/500 contains

The active ingredients are paracetamol and codeine. Each tablet contains 500mg paracetamol and 30mg codeine phosphate hemihydrate.

The other ingredients are sodium hydrogen carbonate, citric acid anhydrous, sodium carbonate, povidone, simeticone, sodium saccharin, aspartame (E951) and polysorbate 80.

What Co-codamol 30/500 look like and the contents of the pack:

Co-codamol 30/500 are white, circular, with a flat bevelled edge and plain on both sides.

Your medicine is available in blister packs of 30, 32, 56, 60, 84, 90 and 100 tablets (not all pack sizes may be marketed)

Marketing Authorisation Holder and Manufacturer:

The Product Licence holder is Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

The manufacturer responsible for batch release:

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