

PACKAGE LEAFLET – INFORMATION FOR THE USER

Co-codamol 30mg/500mg CAPSULES

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.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

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

1. WHAT CO-CODAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-codamol 30mg/500mg Capsules (called co-codamol throughout this leaflet). This medicine has been prescribed for you for the relief of severe pain. Co-codamol 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 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

Important things you should know about co-codamol

- 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.

Warnings and precautions

Do not take co-codamol and tell your doctor 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.
- You have severe asthma attacks or severe breathing problems.
- You have recently had a head injury.
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred vision.
- You have recently had an operation on your liver, gallbladder or bile duct (biliary tract).
- You are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine.
- You are an alcoholic.
- The person going to take the capsules is under 12 years of age. Co-codamol must not be given to children under 12 years of age.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- You know that you metabolise, very rapidly, codeine into morphine.
- You are breastfeeding or planning to breastfeed.

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

Take special care and check with your doctor before taking co-codamol if:

- You are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more of co-codamol 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.
- You have severe kidney or liver problems.
- You have problems passing water or prostate problems.
- You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel.
- You are elderly.
- You have a condition called myasthenia gravis which weakens the muscles.
- You suffer from hypothyroidism.
- You have a disease of the adrenal gland called Addison's disease.
- You are sensitive to aspirin or other medicines used for the treatment of inflammation (Non Steroidal Anti-inflammatory Drugs) such as ibuprofen.
- You are taking a benzodiazepine.
- You know you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable to you.
- You are taking a medicine that induces CYP3A4 enzyme activity such as rifampicin.

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 is 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 sick 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 can affect the way some other medicines work. Also, some other medicines can affect the way co-codamol works.

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 them in the past 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 or benzodiazepines) 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.

Concomitant use of co-codamol 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 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 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.

Please inform your doctor or pharmacist if you are taking:

- 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.

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.

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

Taking co-codamol with food and drink

You should not drink alcohol while you are taking these capsules. This is because taking 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 breastfeeding

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

Driving and using machines

Co-codamol can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive whilst 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 whilst taking this medicine.

Important information about some of the ingredients of your co-codamol capsules

Azorubine: This may cause allergic reactions.

Changing or stopping treatment

Long term usage of co-codamol may lead to tolerance and dependence. If you have taken regular daily doses of co-codamol 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

Your prescriber should have discussed with you, how long the course of capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Always take co-codamol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Do not take more than the recommended dose.**
- **Do not take for longer than your doctor tells you to.**
- **Take this medicine by mouth.**
- **Swallow the capsules whole with a drink of water.**

Adults: 2 capsules every 4 to 6 hours when necessary up to a maximum of 8 capsules in 24 hours. Elderly people may be prescribed a lower dose.

Children aged 16 to 18 years: 1-2 capsules every 6 hours when necessary up to a maximum of 8 capsules in 24 hours.

Children aged 12 to 15 years: 1 capsule every 6 hours when necessary to a maximum of 4 capsules 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.

Children under 12 years:

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

If you take more co-codamol than you should

- Tell your doctor or go to your nearest hospital casualty department straight away - even if you feel well. This is because of the risk of delayed, serious liver damage.
- Remember to take any remaining capsules and the pack with you. This is so the doctor knows what you have taken.

If you have forgotten to take co-codamol

If you forget to take a dose at the right time, take it as soon as you remember. 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

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.

4. POSSIBLE SIDE EFFECTS

As with all medicines, co-codamol 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

- Taking a painkiller for headaches 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 and see a doctor or go to a hospital straight away if:

- You get 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.
- You get serious skin reactions. Very rare cases 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.
- 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, 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, 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

Keep this medicine in a safe place out of the sight and reach of children. Do not use this medicine after the expiry date shown on the pack.

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

Do not store above 25°C.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-codamol 30mg/500mg Capsules contain

- The active substances of Co-codamol 30mg/500mg Capsules are codeine phosphate and paracetamol. Each capsule contains 30mg of codeine phosphate and 500mg of paracetamol.
- The other ingredients are, maize starch, indigotine (E132), azorubine (E122), titanium dioxide (E171), gelatin, black iron oxide (E172), shellac, propylene glycol (E1520), ammonium hydroxide (E527), talc and magnesium stearate.

What Co-codamol 30mg/500mg Capsules look like and contents of pack

Co-codamol 30/500 Capsules are grey and purple with 'COCODAMOL' and '30/500' printed on the capsule in black ink.

They come in cartons of 100 capsules.

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This leaflet was last updated in February 2023

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