

Package leaflet: Information for the user**Co-codamol 30mg/500mg Tablets**
Codeine phosphate 30mg /paracetamol 500mg

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 any further questions, please 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

This medicine has been prescribed for you to relieve from pain. It contains the 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. 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.

2. What you need to know before you take Co-codamol Tablets**Do not take Co-codamol Tablets:**

- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients of this medicine (listed in Section 6: Further information). 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 eyesight.
- 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 (see "Other medicines and Co-codamol Tablets").
- 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.
- If you know that you metabolise very rapidly codeine into morphine.
- If you are breastfeeding.

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.

Warnings and Precautions**Talk to your doctor or pharmacist before taking Co-codamol 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 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.
- have severe kidney or liver problems.
- have problems passing water or prostate problems.
- have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel.
- are elderly.
- are sensitive to aspirin or other medicines used for the treatment of inflammation (Non Steroidal Anti-inflammatory Drugs) such as Ibuprofen.
- are taking a benzodiazepine.
- know you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable to you.
- are taking a medicine that induces CYP3A4 enzyme activity such as rifampicin.
- have a condition called myasthenia gravis which weakens the muscles.

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.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Sleep-related breathing disorders

Co-codamol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep

related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Co-codamol tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Co-codamol if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Co-codamol, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Co-codamol).

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

- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
- 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).

Important things you should know about Co-codamol Tablets

- Do not take for longer than directed by your prescriber.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.
- 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.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. 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.

- 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.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

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.

Do not take this medicine, and tell your doctor, if you are taking

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Tell your doctor or pharmacist if you are taking any of the following medicines, or have taken them in the past two weeks:

- Medicines which make you drowsy or sleepy (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.
- Anti-depressant medicines such as imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine.
- Antihistamine medicines used to treat allergies.

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.

Co-codamol Tablets with food, drink and alcohol

If your diet is poor or you have a low protein intake, you may be at a higher risk of serious paracetamol poisoning when taking Co-codamol tablets.

Do not drink alcohol whilst taking Co-codamol tablets.

Pregnancy, Breast-feeding and Fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 breast-feeding as codeine passes into breast milk and will affect your baby

Driving and using machines

Co-codamol tablets may cause dizziness, blurred vision or the inability to think clearly. Make sure you are not affected before you drive or operate machinery.

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. If you feel dizzy or sleepy, do not use any tools or machines.

Co-codamol Tablets contain sodium metabisulfite

- Co-codamol Tablets contain sodium metabisulfite (E223) which may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (tightening of the airways)

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Co-codamol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Co-codamol).

Co-codamol should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

Method of administration:

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.

Doses:

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.

Adults:

The recommended dose is 1 to 2 tablets for at least 4 hours before taking another dose. Do not take more than 8 tablets in 24 hours.

Elderly: lower doses may be more suitable.

Children aged 16 years to 18 years:

Children aged 16 years or above should take 1 to 2 tablets every 6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children aged 12 years to 15 years:

The recommended dose for children aged 12 years to 15 years is 1 tablet every 6 hours when needed. Do not take more than 4 tablets in 24 hours.

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

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. Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

Symptoms of an overdose include feeling or being sick, loss of appetite, stomach pain or liver damage, coma, pale or clammy skin, fits, confusion, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow heart beat or breathing rate.

If you forget to take Co-codamol Tablets

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 a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

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.

4. Possible Side effects

Like all medicines, this medicine 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.
- Not known: dependence and addiction (see section "How do I know if I am addicted?").
- problem affecting a valve in the intestines (sphincter of Oddi dysfunction)

Stop taking Co-codamol and see a doctor or go to a hospital straight away if:

- 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.
- 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.
- Not known: A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 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 Website: 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.
- Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date (EXP.) as shown on the carton. The expiry date refers to the last day of that month.
- 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 protect the environment.

6. Contents of the pack and other information

What Co-codamol Tablets contain

- Each tablet contains 30 mg of codeine phosphate and 500 mg of paracetamol
- The other ingredients are: pregelatinised maize starch, microcrystalline cellulose, sodium starch glycolate, sodium metabisulfite (E223), magnesium stearate.

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

- White to off white capsule shaped biconvex uncoated plain tablets, debossed with '30' on one side and 'BL' on other side.
- They are available in packs of 8's, 10's, 16's, 20's, 30's, 32's and 100's tablets. Not all pack sizes may be marketed.

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