

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and seek immediate medical help if you experience any of the following serious side effects:

Very rare (may affect up to 1 in 10,000 people):

- severe skin reaction, such as reddening of the skin with blisters or peeling and may be associated with a high fever and joint pain
- severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis).

Not known (frequency cannot be estimated from the available data):

- swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing, rashes which are itchy or lumpy (hives), or nettle rash (urticaria). This may mean you are having an allergic reaction to this medicine
- fits (seizures)
- difficulty breathing and dizziness
- 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:

Not known (frequency cannot be estimated from the available data):

- constipation, feeling sick (nausea), being sick (vomiting), dry mouth
- dizziness, light-headedness, drowsiness, confusion
- pain and difficulty passing urine
- infections or bruising more easily than usual. This could be because of a blood problem
- feelings of unease or dissatisfaction, overwhelming feeling of happiness and well-being, restlessness, irritability, headache, excessive drowsiness or sleeping
- excessive constriction (shrinking) of the pupil of your eye and drooping eyelid
- 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)
- a problem affecting a valve in the intestines (sphincter of Oddi dysfunction).

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. Store below 25°C in a dry place, protected from light.

Do not take this medicine after the expiry date which is stated on the label/carton/bottle. 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

- The active substances are codeine phosphate and paracetamol. Each tablet contains 8mg of codeine phosphate and 500mg paracetamol.
- The other ingredients are colloidal anhydrous silica, maize starch, pregelatinised maize starch, stearic acid.

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

Co-codamol tablets are white, circular, flat bevelled-edge uncoated tablets, impressed 'C' and the identifying letters 'CH' on either side of a central division line on one face.

Pack sizes are 30 and 32.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

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Package leaflet: Information for the patient

Co-codamol Tablets 8/500mg

(Codeine Phosphate and Paracetamol)

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- **This medicine can only be used for the short term treatment of acute moderate pain which is not relieved** by paracetamol, ibuprofen or aspirin alone. Do not take less than four hours after taking other painkillers.
- **Co-codamol tablets should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.**
- **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.
- **This medicine contains paracetamol.** Do not take anything else containing paracetamol while taking this medicine.
- **If you take this medicine for headaches for more than three days it can make them worse.**
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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

Co-codamol is an analgesic (painkiller), used for the short-term treatment of acute moderate pain caused by headaches, migraine, toothache, neuralgia, period pain

and rheumatic pains when other painkillers have not worked. Wait at least 4 hours after you last took other painkillers before taking this medicine.

Co-codamol tablets can be used in adults and 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.

This medicine 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.

2 What you need to know before you take Co-codamol tablets

- **This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.**
- **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 (see 'If you stop taking Co-codamol tablets').**
- **If you take a painkiller for headaches for more than three days it can make them worse.**

Do not take Co-codamol tablets:

- 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 (see **'Other medicines and Co-codamol'**)
- if you are **allergic** to paracetamol, codeine phosphate, or any of the other ingredients of this medicine (listed in section 6)
- if the person going to take the tablets is **under 12 years of age**. Co-codamol must not be given to children under 12 years of age
- 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 codeine into morphine** very rapidly
- if you are **breast-feeding**

Warnings and precautions

Talk to your doctor or pharmacist before taking

Co-codamol tablets if you:

- have liver or kidney problems
- suffer from seizures
- have a condition called myasthenia gravis which weakens the muscles.

During treatment with Co-codamol tablets, tell your doctor straight away 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)
- experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine
- 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.

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 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 tablets if you:

- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker.
- 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 tablets 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 tablets).

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.

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.

Use in children and adolescents after surgery

Co-codamol 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

Co-codamol is not recommended in children with breathing problems (may be seen in children with neuromuscular disorders, severe heart or lung conditions, upper respiratory or lung infections, multiple trauma or after extensive surgical procedures), 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 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 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
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

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 also increases the risk of 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.

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

- Medicines used to thin the blood e.g. warfarin.
- Metoclopramide or domperidone (used to stop you feeling sick (nausea) or being sick (vomiting)).
- Colestyramine (for lowering blood cholesterol levels).
- 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.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

Co-codamol tablets and alcohol

Drinking alcohol whilst taking co-codamol may result in drowsiness, difficulties in breathing, coma and may be life-threatening. It is recommended not to consume alcohol while you are taking Co-codamol tablets.

Pregnancy and breast-feeding

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.

Pregnancy

Do not take Co-codamol tablets during pregnancy, unless advised by your doctor. Regular use during pregnancy may cause breathing problems and withdrawal symptoms in the newborn.

Breast-feeding

Do not take Co-codamol tablets while you are breast-feeding. Codeine and morphine pass into breast milk.

Driving and using machines

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

- Do not drive or operate machinery 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 this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with **water**.

Do not take for more than 3 days. Co-codamol tablets should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.

The recommended dose is

- **Adults:** 2 tablets every 4 to 6 hours, as needed. Do not take more than 8 tablets in 24 hours
- **Children 16 to 18 years:** 1 to 2 tablets every 6 hours, as needed. Do not take more than 8 tablets in 24 hours
- **Children aged 12 to 15 years:** 1 tablet every 6 hours, as needed. Do not give your child more than 4 tablets in 24 hours
- **Children under 12 years:** Should not be taken due to the risk of severe breathing problems
- **Elderly:** Dosage is usually reduced in the elderly with liver damage.

If you take more Co-codamol tablets than you should

Seek immediate medical advice in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you (or someone else) take more tablets than you should, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, loss of appetite, stomach pain, coma, pale skin, low blood pressure, pinpoint pupils, irregular, slow or fast heartbeat, difficulty breathing, liver or kidney damage.

If you forget to take Co-codamol tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Remember to leave at least 4 to 6 hours between doses for adults and 6 hours for children aged 12 to 18 years.

If you stop taking Co-codamol tablets

This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get **withdrawal symptoms** such as tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.