

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.
- **You should only take this product for a maximum of three days** at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice.
- **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.

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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 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
- 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** very rapidly **codeine into morphine**
- 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
- are taking a benzodiazepine
- suffer from seizures.

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.

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 any of the following medicines, or have taken them in the past two weeks:

- Medicines which make you drowsy or sleepy (e.g. CNS depressants or a benzodiazepine) such as other pain relievers, sleeping tablets, cough medicines, antihistamines, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety, high blood pressure or anaesthetics.

- Anti-depressant medicines (e.g. imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine).

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.

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).

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 take alcohol while you are taking Co-codamol tablets.

Pregnancy and breast-feeding

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

This 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 your doctor has 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. If the pain does not improve after 3 days, talk to your doctor for advice.

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) swallow a lot of tablets at the same time, 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.

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.

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

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.

Talk to your doctor straight away if you notice any of the following serious side effects:

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

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

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).

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.

How do I know if I am addicted?

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time.
- You need to take more than the recommended dose.
- When you stop taking the medicine you feel very unwell, but you feel better if you start taking the medicine again.

5 How to store Co-codamol tablets

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

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 require. These measures will help protect the environment.

6 Contents of the pack and other information

What Co-codamol tablets contain

- The active substances (the ingredients that makes the tablets work) are 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, 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.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in April 2021