**PACKAGE LEAFLET – INFORMATION FOR THE USER**

# CO-CODAMOL 8/500 TABLETS

Codeine Phosphate and Paracetamol

**⚠ Important things you should know about co-codamol**

- **This medicine can only be used for the short term treatment of acute moderate pain when other painkillers have not worked**
- **You should only take this product for a maximum of 3 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 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it**
- **If you take this medicine for headaches for more than 3 days it can make them worse**

**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, ask your doctor or pharmacist
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet

**What is 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 8/500 Tablets (called co-codamol throughout this leaflet).
Co-codamol contains two different medicines called codeine phosphate and paracetamol. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol. Co-codamol is 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 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

⚠
- **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 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it**
- **If you take a painkiller for headaches for more than 3 days it can make them worse**

**Warnings and precautions**

**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 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).

**Do not take co-codamol 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
- You are allergic to the active substances 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
- 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
- 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 applies 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 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 taking a benzodiazepine
- You suffer from seizures
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

**During treatment with co-codamol, 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).

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.

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.

**Children and adolescents**
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, since the symptoms of morphine toxicity may be worse in these children.

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

**Other medicines and co-codamol**
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 products. This is because co-codamol and other medicines can affect the way each other 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 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
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

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.

**While taking co-codamol you should not take any other medicines which contain paracetamol.** 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:**

- 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 other medicines:**
- Medicines used to thin the blood such as warfarin.
- Chloramphenicol – an antibiotic used for infections.
- Antiemetics such as metoclopramide or domperidone – used for travel sickness or to stop you feeling sick (nausea), or being sick (vomiting).
- Medicines to treat psychiatric disorders (antipsychotics or neuroleptics).
- Muscle relaxants.
- Medicines to treat Parkinson's disease.
- Colestyramine – for lowering blood cholesterol levels.
- The oral contraceptive pill.

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

**Pregnancy and breast-feeding**
Talk to your doctor before taking these tablets if:
- You are pregnant, think you may be pregnant or plan to get pregnant
- You are planning to breastfeed
- Do not take co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.

If necessary, Co-codamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

**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.

## 3. HOW TO TAKE CO-CODAMOL

Always take co-codamol exactly as instructed on the leaflet. Check with your doctor or pharmacist if you are not sure.
- Do not take more than the recommended dose.
- Swallow the tablets whole with a drink of water.

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

**Use in children aged 16 to 18 years:**
1 to 2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

**Use in children aged 12 to 15 years:**
1 tablet every 6 hours when necessary to a maximum of 4 tablets 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.

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

Co-codamol 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.

**If you take more co-codamol 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.

**If you forget to take co-codamol**
If you forget to take a dose at the right time, take it as soon as you remember. However 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**
**This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.**

## 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:

**Stop taking co-codamol and see a doctor or go to a hospital straight away if:**
- 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.
- You have a fit (seizure).
- You have difficulty breathing and you feel dizzy.

**Talk to your doctor straight away if you notice any of the following serious side effects:**
- 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), dry mouth
- Dizziness, light-headedness, drowsiness, confusion
- Feeling overly happy (euphoria)
- A feeling of unease or dissatisfaction
- Excessive constriction (shrinking) of the pupil of your eye
- Difficulty in passing water
- You get infections or bruise more easily than usual. This could be because of a blood problem
- Becoming addicted to codeine

**Not known** (frequency cannot be estimated from the available data):
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).
- 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 or pharmacist. 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.

**How do I know if I am addicted?**
**If you take this 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 this medicine you feel very unwell but you feel better if you start taking the medicine again**

## 5. HOW TO STORE CO-CODAMOL

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.
Store your medicine in the original packaging in order to protect from moisture.
Do not store above 25°C.

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 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 8/500 Tablets contain**
- The active substances are codeine phosphate and paracetamol. Each tablet contains 8mg of codeine phosphate and 500mg of paracetamol.
- The other ingredients are maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, talc, pregelatinised starch and purified water.

**What Co-codamol 8/500 Tablets look like and contents of the pack**
Flat white tablets, marked S/4 on one side. They come in cartons of 32 tablets.

**The Marketing Authorisation Holder is:**
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

**The Manufacturer is:**
Zentiva Pharma UK Limited, First Floor, Andrews House, College Road, Guildford, GU1 4QB. United Kingdom
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