

Package leaflet: Information for the patient
CO-CODAMOL 8 MG/500 MG EFFERVESCENT TABLETS

Codeine phosphate hemihydrate and paracetamol

The name of this medicine is Co-codamol Effervescent Tablets 8/500 mg, which will be referred to as Co-codamol 8/500 throughout this leaflet.

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 has 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.
- 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.**
- **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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Co-codamol 8/500 is and what it is used for
2. What you need to know before you take Co-codamol 8/500
3. How to take Co-codamol 8/500
4. Possible side effects
5. How to store Co-codamol 8/500
6. Content of the pack and other information

1. What Co-codamol 8/500 is and what it is used for

The active ingredients in Co-codamol 8/500 are paracetamol and codeine phosphate hemihydrate.

Co-codamol 8/500 is for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. It is used to relieve muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache, period pains, aches and pains.

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.

Codeine 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 8/500

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.

If you take this medicine for headaches for more than three days it can make them worse.

Do not take Co-codamol 8/500 if you:

- are **allergic to paracetamol, codeine** or any of the **other ingredients** of this medicine (listed in section 6).
- have a **dependency to alcohol**
- have **difficulty breathing or other chronic lung disease**
- are having an **asthma attack**
- have **bowel problems**
- have **raised intracranial pressure or head injury.**
- 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
- know that you metabolise very rapidly codeine into morphine
- are breastfeeding

Warnings and precautions

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. 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 8/500 can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. If you are taking Co-codamol 8/500 for longer than the recommended time or at higher than recommended doses the risk of these side effects can increase and you are also at risk of serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

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 8/500 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 8/500, 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 8/500)

Talk to your doctor or pharmacist before taking Co-codamol 8/500 if you

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

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

During treatment with Co-codamol 8/500 tell your doctor straight away if:

- 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).

Talk to your doctor if you experience any of the following symptoms while taking Co-codamol 8/500

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

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 8/500 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

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.

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Other medicines and Co-codamol 8/500

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription, as they may decrease or increase the effect of Co-codamol 8/500. 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

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

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

You may experience more drowsiness if you take these medicines with co-codamol.

Do not take these tablets if you are already taking other medicines containing paracetamol.

- metoclopramide or domperidone (often taken for sickness or stomach problems)
- colestyramine (for high blood lipid levels)
- anticoagulants to reduce blood clotting (e.g. warfarin)

Please inform 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).

If you are unsure about interactions with any other medicines, talk to your pharmacist.

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CO-CODAMOL
EFFERVESCENT TABLETS
8/500 mg



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CO-CODAMOL
EFFERVESCENT TABLETS
8/500 mg



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Font: Arial
Arial Bold

Body text : 9pt
Sub Heading : 10pt
Main Heading : 12pt
Justification : Left

SAP Code: XXXXXXXX (Ver. 01)
Actual Size: 297 x 400 mm
Size after folding: 50 x 46 mm
Colours:
■ Black
Supersedes: 21102096
2D code : XXXXXXXX
CR :
Country : UK
Type : Safety
Date: 23/01/2025

Co-codamol 8/500 with food and drink

Co-codamol 8/500 should be dissolved in at least half a glass of water and can be taken with or without a meal.

Pregnancy and breast-feeding

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

Although there is no evidence that these tablets cause any ill effects during pregnancy, your doctor should advise you about taking them if you are pregnant.

Do not take codeine when you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machinery

These tablets may make you feel dizzy or drowsy and if this happens do not 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.

Co-codamol 8/500 contains sodium and aspartame

This medicine contains 438 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 21.9% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 5 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Co-codamol 8/500

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended doses.

If Co-codamol 8/500 has been prescribed to you, Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Co-codamol 8/500, 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 8/500).

Dosage

The usual dose for Co-codamol 8/500 is as follows:

- Adults over 18 years:

One to two tablets dissolved in water every 4 to 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

- Children aged 16 years to 18 years:

One to two tablets dissolved in water every 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

- Children aged 12 years to 15 years:

One tablet dissolved in water every 6 hours as needed.

Do not take more than 4 tablets in 24 hours.

Elderly:

Elderly people may be prescribed a lower dose.

This medicine should not be taken for more than 3 days. If the pain does not improve after days, talk to your doctor for advice.

Use in children

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

Method of Administration

For oral administration only. Co-codamol should be dissolved in at least half a glass of water. The resulting solution should be stirred well before oral administration. These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Co-codamol 8/500 than you should:

If you have accidentally taken more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

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.

If you forget to take Co-codamol 8/500

If you forget to take one or more doses, take your next dose when you remember and then go on as prescribed. Do not take a double dose to make up for a forgotten dose.

Withdrawal symptoms:

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. 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, Co-codamol 8/500 can cause side-effects although not everybody gets them.

If you get any of the following symptoms after taking these tablets, **you should contact your doctor immediately**:

Important side effects you should know about Co-codamol 8/500

- **Long-term usage of high doses of codeine + paracetamol can be rarely associated with sensorineural hearing loss.**

Page 3

- **Any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.**
- **An acute allergic reaction (anaphylaxis) or swelling of the skin**
- **Rarely pancreatitis (inflammation of the pancreas which may cause severe abdominal pain that can spread through to your back)**
- **Very rare cases of serious skin reactions have been reported.**

The following effects have been reported:

- Skin rashes
- Constipation
- Nausea, vomiting
- Light-headedness, dizziness
- Confusion
- Headache
- Abdominal pain
- Drowsiness
- Urinary retention

There have been very rare reports of blood problems, so if you notice unusual bleeding or you bruise easily or have more fevers or infections (such as sore throats) than usual tell your doctor as soon as possible.

Frequency - 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)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

Important side effects you should know about Co-codamol 8/500

- Taking a painkiller for headache too often or for too long can make them worse.
- 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

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

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: <https://yellowcard.mhra.gov.uk/> 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 8/500

Do not store your tablets above 25°C. Store in a dry place and protect from light.

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 take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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

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. Content of the pack and other information

What Co-codamol 8/500 mg Effervescent Tablets contain:

The active ingredients are paracetamol and codeine phosphate hemihydrate. Each tablet contains 500mg paracetamol and 8mg codeine phosphate hemihydrate.

The other ingredients are sodium hydrogen carbonate, citric acid, sodium carbonate, povidone, simeticone, sodium saccharin, aspartame (E951) and polysorbate 80.

What Co-Codamol 8/500 look like and the contents of the pack:

Co-codamol 8/500 mg Effervescent Tablets are white, circular, with a flat bevelled edge and plain on both sides.

Your medicine is available in blister packs of 7, 10, 14, 20, 28, 30 and 32 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer:

The Product Licence holder is Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

The manufacturer responsible for batch release:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

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Page 4