

Package Leaflet: Information for the user

Co-codamol 15mg/500mg Capsules (Codeine Phosphate Hemihydrate and Paracetamol)

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, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Co-codamol 15mg/500mg Capsules are and what they are used for
2. What you need to know before you take Co-codamol 15mg/500mg Capsules
3. How to take Co-codamol 15mg/500mg Capsules
4. Possible side effects
5. How to store Co-codamol 15mg/500mg Capsules
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1. What Co-codamol 15mg/500mg Capsules are and what they are used for

Co-codamol 15mg/500mg Capsules are used to relieve moderate 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.

This medicine has been prescribed for you for pain relief. It contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. 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. It also contains paracetamol, another analgesic to relieve pain.

2. What you need to know before you take Co-codamol 15mg/500mg Capsules

Do not take Co-codamol 15mg/500mg Capsules if you

- are allergic to codeine phosphate hemihydrate, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- are suffering from increased pressure on the brain or a head injury.

- have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- are having (or have recently had) a severe but short lasting asthma attack (acute asthma) or any other breathing problems, for example chronic bronchitis or emphysema.
- consume excessive amounts of alcohol on a regular basis.
- are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). Ask your doctor or pharmacist if you are not sure what types of medicine you are taking.
- are pregnant or breast-feeding.
- know that you metabolise very rapidly codeine into morphine.
- have recently had an operation on your liver, gallbladder or bile duct (biliary tract).
- suffer from severe kidney or liver disease.

Talk to your doctor if any of the above apply to you.

Do not use this product 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.

Do NOT give this product to children under 12 years of age.

Warnings and precautions

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.

Talk to your prescriber before taking this medicine 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 Co-codamol 15mg/500mg Capsules 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.

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.

Also, talk to your doctor, pharmacist or nurse before taking Co-codamol 15mg/500mg Capsules if you

- are elderly and/or in poor health
- suffer from an enlarged prostate
- suffer from narrowing of your urethra (tube through which urine is passed)
- suffer from any bowel problems
- suffer from seizures (fits)
- have an underactive thyroid gland
- have a condition which weakens the muscles called myasthenia gravis
- suffer from Addison's disease
- suffer from any liver or kidney problems
- weigh less than 50kg
- suffer from chronic malnutrition or dehydration
- have a condition that prevents production of a molecule called glutathione.

If any of the above apply to you, it is important that you speak to your doctor or pharmacist before taking this medicine and they will decide what to do. It may still be safe for you to take this medicine.

- Do not take for longer than directed by your prescriber.
- Taking a painkiller for headaches too often or for too long can make them worse.

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

During treatment with Co-codamol 15mg/500mg Capsules, tell your doctor straight away if any of the following applies to you. 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).

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 15mg/500mg Capsules

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:

- medicines called Monoamine Oxidase Inhibitors (MAOIs) used to treat depression, or have taken them in the last two weeks (see section 2 “Do not take Co-codamol 15mg/500mg Capsules...”). MAOIs are medicines such as moclobemide, phenelzine and tranylcypromine.
- sedative medicines such as benzodiazepines or related drugs, including those used for depression, anxiety, medicines known as tranquillisers, or hypnotics (medicines to help you sleep). Taking these medicines with Co-codamol 15mg/500mg Capsules increases the risk of drowsiness, difficulties in breathing (respiratory depression) and 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 15mg/500mg Capsules 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.
- medicines to help relax muscles (e.g. baclofen).
- medicines for irregular heartbeat (e.g. mexiletine, quinidine).
- fluoxetine or paroxetine (used to treat anxiety or depression).
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- domperidone or metoclopramide (medicines to stop you feeling sick or vomiting). The speed of absorption of paracetamol may be increased by these medicines.
- colestyramine (medicine for high cholesterol levels or diarrhoea). The absorption of paracetamol is reduced by this medicine.
- medicines used to treat seizures (carbamazepine, phenytoin, phenobarbital, primidone).
- rifampicin (an antibiotic used for infections).
- herbal medicines containing St John’s wort.
- anticoagulants, e.g. warfarin (medicine to prevent blood clots). There may be an increased risk of bleeding caused by prolonged regular use of paracetamol.
- other strong painkillers called opioids.
- medicines that you have bought yourself such as cough/cold remedies or other painkillers. Many of these will contain paracetamol and/or codeine and should not be taken while you are taking Co-codamol 15mg/500mg Capsules.

Co-codamol 15mg/500mg Capsules with food and alcohol

You should avoid alcohol when taking this product.

Food has no influence on Co-codamol 15mg/500mg Capsules.

Pregnancy and breast-feeding

Do not take Co-codamol 15mg/500mg Capsules if you are pregnant or think you might be pregnant.

Do not take Co-codamol 15mg/500mg Capsules while you are breast-feeding as codeine passes into breast milk and will affect your baby.

Driving and using machines

Co-codamol 15mg/500mg Capsules may make you feel drowsy. Do not drive or use machines until you know how they affect you.

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 15mg/500mg Capsules contain Cochineal Red A (E124) and sodium

Cochineal Red A (E124) may cause allergic reactions.

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

3. How to take Co-codamol 15mg/500mg Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your prescriber should have discussed with you, how long the course of Co-codamol 15mg/500mg Capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

The recommended dose for adults and the elderly is one or two capsules taken every four hours. You should not take more than eight capsules in any 24-hour period.

Use in children and adolescents

The recommended dose for children aged 16 and over is one or two capsules taken every six hours. You should not take more than eight capsules in any 24-hour period.

The recommended dose for children aged 12 to 15 years is one capsule taken every six hours, up to a maximum of four capsules in any 24-hour period.

This medicine should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

A lower dosage may be needed if you are elderly or have other medical problems. Check with your doctor about this.

If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Co-codamol 15mg/500mg Capsules should be taken orally (by mouth).

This medicine should only be taken when necessary. Do not take more than the stated dose and do not take for more than three days. If the pain does not improve after three days, talk to your doctor for advice.

If you take more Co-codamol 15mg/500mg Capsules than you should

It is always important to follow the dose recommended on the label. 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 15mg/500mg Capsules

If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take this medicine any more. However, if you still suffer from pain take your dose as soon as you remember and then carry on as before. It is important that you do not take a double dose to make up for the forgotten dose.

If you stop taking Co-codamol 15mg/500mg Capsules

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.

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

4. Possible side effects

Like all medicines, Co-codamol 15mg/500mg Capsules can cause side effects, although not everybody gets them.

If you experience any of these symptoms please tell your doctor or pharmacist immediately:

- allergic reaction (skin rash, itching, swelling or shortness of breath)
- serious skin reactions (very rare cases of serious skin reactions have been reported)
- sudden pain in the upper part of your abdomen, if you have previously had your gall bladder removed
- signs of bronchospasm such as difficulty in breathing, shortness of breath, wheezing, tightness in the chest (more likely to occur in those with asthma who are sensitive to medicines used to treat inflammation, such as aspirin)

The following side effects have been reported:

- feeling sick or vomiting
- dizziness or drowsiness

Lying down may relieve these effects.

- slow heart beat
- narrowing of your pupils
- constipation
- stomach pains
- light-headedness
- headache
- slow or weak breathing
- hallucination
- confusion or changes in your mood
- bladder problems
- itchy skin or itchy, raised rash (hives)
- low blood cell counts (platelets and white blood cells) but these were not necessarily related to paracetamol
- dependence and addiction (see section “How do I know if I am addicted?”)
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). The frequency of metabolic acidosis is not known (cannot be estimated from the available data).

Drug Withdrawal

When you stop taking Co-codamol 15mg/500mg Capsules, 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 15mg/500mg Capsules, 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 15mg/500mg Capsules

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

Do not use this medicine after the expiry date, which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use this medicine if you notice that the pack or any of the capsules are damaged.

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 15mg/500mg Capsules contain

The active substances are codeine phosphate hemihydrate and paracetamol. Each capsule contains 15mg of codeine phosphate hemihydrate and 500mg of paracetamol.

The other ingredients are sodium starch glycolate (type A) and magnesium stearate.

The capsule shells contain gelatin, and the colourings titanium dioxide (E171), cochineal red A (E124) (see section 2 “Co-codamol 15mg/500mg Capsules contain ...” for information about this ingredient) and brilliant blue (E133). The ink markings on the capsule shell contain shellac, black iron oxide (E172) and propylene glycol.

What Co-codamol 15mg/500mg Capsules look like and contents of the pack

Co-codamol 15mg/500mg Capsules are hard gelatin capsules (size 0) with a red cap and a white body. Both sides are marked in black ink with “G15/500”.

Co-codamol 15mg/500mg Capsules are available in packs of 20, 60 and 100 capsules. Not all of these pack sizes are marketed.

Marketing Authorisation Holder

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Seagoe Industrial Estate
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Manufacturer

Almac Pharma Services Limited
Almac House
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