

## **Package Leaflet: Information for the user**

### **Co-codamol 15mg/500mg Tablets** (Codeine Phosphate Hemihydrate and Paracetamol)

**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 Tablets are and what they are used for
2. What you need to know before you take Co-codamol 15mg/500mg Tablets
3. How to take Co-codamol 15mg/500mg Tablets
4. Possible side effects
5. How to store Co-codamol 15mg/500mg Tablets
6. Contents of the pack and other information

#### **1. What Co-codamol 15mg/500mg Tablets are and what they are used for**

Co-codamol 15mg/500mg Tablets 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 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 15mg/500mg Tablets**

##### **Do not take Co-codamol 15mg/500mg Tablets:**

- if you are allergic to codeine phosphate hemihydrate, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you are suffering from increased pressure on the brain or a head injury.
- if you have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- if you are having (or have recently had) a severe but short-lasting asthma attack (acute asthma).
- if you consume excessive amounts of alcohol on a regular basis.

- if you 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.
- if you are pregnant or breast-feeding.
- if you know that you metabolise very rapidly codeine into morphine.

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 doctor, pharmacist or nurse before taking Co-codamol 15mg/500mg Tablets:

- if you are elderly and/or in poor health
- if you suffer from an enlarged prostate
- if you suffer from any bowel problems
- if you suffer from Addison's disease
- if you suffer from any liver or kidney problems.

If any of the above apply to you, it is important that you speak to your doctor, pharmacist or nurse 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 codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- 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.

### **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 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:

- 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 Tablets...”). MAOIs are medicines such as moclobemide, phenelzine and tranylcypromine.
- sedative medicines such as benzodiazepines or related drugs, including those used for depression, anxiety, other medicines known as tranquillisers, or hypnotics (medicines to help you sleep). Taking these medicines with Co-codamol 15mg/500mg Tablets 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 Tablets 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.
- 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.
- 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.
- anticoagulants, e.g. warfarin (medicine to prevent blood clots). There may be an increased risk of bleeding caused by prolonged regular use of paracetamol.
- 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 Tablets.

### **Co-codamol 15mg/500mg Tablets with food and alcohol**

You should avoid alcohol when taking this product.

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

### **Pregnancy and breast-feeding**

Do not use this product or any other codeine-containing products if you are pregnant.

Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.

### **Driving and using machines**

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

This 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 Tablets contain sodium**

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

### **3. How to take Co-codamol 15mg/500mg Tablets**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

#### **Use in children and adolescents**

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

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

Doctors sometimes prescribe different doses to these. Read the pharmacist's label, it will tell you exactly how many you should take.

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

This medicine should be taken orally (by mouth). The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 Tablets 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 Tablets**

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 Tablets**

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.

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, this medicine 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

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
- confusion or changes in your mood
- bladder problems
- itchy skin
- low blood cell counts (platelets and white blood cells) but these were not necessarily related to paracetamol

### **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](http://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 Tablets**

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.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack or any of the tablets 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 Tablets contain**

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

The other ingredients are microcrystalline cellulose, povidone, sodium starch glycolate and magnesium stearate.

### **What Co-codamol 15mg/500mg Tablets look like and contents of the pack**

Co-codamol 15mg/500mg Tablets are oblong, white uncoated tablets. One side has the markings 'K1' on both sides of a score line, the other side has no markings.

Co-codamol 15mg/500mg Tablets are available in packs of 4, 30 and 100 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Galen Limited  
Seagoe Industrial Estate  
Craigavon  
BT63 5UA  
UK

### **Manufacturer**

Almac Pharma Services Limited  
Almac House  
20 Seagoe Industrial Estate  
Craigavon  
BT63 5QD  
UK

Almac Pharma Services (Ireland) Limited  
Finnabair Industrial Estate  
Dundalk  
Co Louth  
A91 P9KD

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