

## Package Leaflet: Information for the Patient

### Co-codamol 15mg/500mg Capsules codeine phosphate/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 or pharmacist.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The product is known by the name above but will be referred to as Co-codamol Capsules throughout the rest of this leaflet.

#### **What is in this leaflet**

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

#### **1. What Co-Codamol Capsules are and what they are used for**

This medicine has been prescribed for you for relief of moderate pain. Co-codamol Capsules contains codeine. Codeine belongs to a class of medicines called opioid, which are ‘pain relievers’. It also contains Paracetamol which is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). Co-codamol Capsules 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 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.

#### **2. What you need to know before you take Co-Codamol Capsules**

Do not take with any other paracetamol-containing products. 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.

**Do not take Co-codamol Capsules if**

- you are allergic to paracetamol or codeine, or any of the other ingredients (refer to section 6 below)
- you suffer from severe kidney or liver disease
- you know that you metabolise very rapidly codeine into morphine
- you are breast-feeding
- you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs such as phenelzine or isocarboxazid are medicines used to treat depression
- you have just had a head injury or suffer from increased pressure on the brain
- you drink a lot of alcohol, or have done in the past
- you have recently had an operation to your gall bladder.
- children under 12 years of age.

Do not use Co-codamol Capsules for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Co-codamol Capsules may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Co-codamol Capsules if:

- you are elderly or weak
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have liver, kidney or thyroid problems, because the dose might need to be lower
- you have a condition called myasthenia gravis which weakens the muscles
- you have problems with your adrenal glands (Addison's disease – your doctor will advise you)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)

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 of Co-codamol 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.

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.

## **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 (sleep disruption due to respiratory pauses). They may be at increased risk of severe side effects in case of morphine toxicity.

### **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 Capsules**

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

Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics
- medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- other strong painkillers called opioids

- medicines which prevent blood clotting (anticoagulants such as warfarin)
- Co-codamol Capsules must not be taken with any other medicines containing paracetamol or codeine. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Co-codamol Capsules can interfere with some laboratory tests used for determining some diseases.

The CNS depressant action of this medicine may be enhanced by coadministration with any other drug which has a CNS depressant effect (e.g. anxiolytics, hypnotics, antidepressants, antipsychotics and alcohol). Concomitant use of any drug with a CNS depressant action should be avoided. If combined therapy is necessary, the dose of one or both agents should be reduced.

Concomitant use of Co-codamol Capsules 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 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.

### **Co-codamol Capsules with food, drink and alcohol**

Do not drink alcohol whilst taking Co-codamol Capsules.

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

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

#### **Pregnancy**

Do not take Co-codamol Capsules if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Co-codamol Capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

#### **Breast-feeding**

Do not take Co-codamol Capsules while you are breastfeeding as codeine passes into breast milk and will affect your baby.

### **Driving and using machines**

Co-codamol Capsules may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

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 Capsules contains sodium**

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

### **3. How to take Co-Codamol 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 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 is:

Adults: The recommended dose is one or two capsules every four to six hours as required up to a maximum of 8 capsules in any 24 hour period.

If you feel the effect of Co-codamol Capsules is too strong or too weak, speak to your doctor or pharmacist. 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. A lower dosage may be needed if you are elderly or have other medical problems. Check with your doctor about this. Do not take with any other Paracetamol containing products.

Elderly: A reduced dosage may be necessary.

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

**Children aged 16-18 years:** The recommended dose is one to two capsules every 6 hours when necessary up to a maximum of 8 capsules in 24 hours.

**Children aged 12 – 15 years:** The recommended dose is one capsule every 6 hours when necessary up to a maximum of 4 capsules in 24 hours.

Co-codamol Capsules should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

### **If you take more Co-codamol Capsules than you should**

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Bring the remaining capsules and this leaflet with you so that the medical staff knows what you have taken.

Symptoms of paracetamol overdose are usually seen in the first 24 to 48 hours, such as pale appearance of the skin, nausea, vomiting, loss of appetite and pain in the abdomen. In severe poisoning, liver failure may occur which may progress to change in mental status, signs of bleeding, low blood sugar, brain swelling, and death. Kidney failure suggested by symptoms of flank pain, blood in the urine or frothy urine (excess proteins in the urine), may be seen even in the absence of severe liver damage.

Symptoms of codeine overdose are usually seen when very large dosage are ingested, or other sedative agents have been co-ingested including alcohol. There may be brain function slow down and depressed or difficulty in breathing. Pin-point pupils; nausea and vomiting are common symptoms. Low blood pressure and increased heart rate may be possible.

### **If you forget to take Co-codamol Capsules**

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Co-codamol 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 or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Stop taking the medicine and seek immediate medical advice if you notice the following:**

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, skin rashes, redness or itching (especially affecting your whole body) should be reported to a doctor immediately.

### **Possible side effects are**

- feeling sick (nausea) and being sick (vomiting)
- light headedness, dizziness, sleepiness
- shortness of breath
- stomach pains, constipation.

Lying down may help these effects if they happen.

**Other side effects include**

**Common: may affect up to 1 in 10 people**

- Headaches, dizziness, light-headedness and sedation
- Nausea, vomiting and constipation

**Uncommon: may affect up to 1 in 100 people**

- Drug Withdrawal

When you stop taking Co-codamol 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.

**Not known: frequency cannot be estimated from the available data**

- a feeling of extra well being, or feel lost or confused
- small eye pupils, problems with vision
- slowing of the pulse
- difficulty in passing urine
- liver damage, especially in heavy drinkers
- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting
- problems with breathing
- dependence and addiction (see section “How do I know if I am addicted?”).

**How do I know if I am addicted?**

If you notice any of the following signs whilst taking Co-codamol 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.

If a pain killer is used too long for headaches, it can make them worse.

**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 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 after EXP. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25°C.

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 to protect the environment.

## **6. Contents of the pack and other Information**

### **What Co-codamol Capsules contain**

- the active substances are paracetamol 500mg and codeine phosphate 15mg
- the other ingredients are maize starch, sodium lauryl sulfate, cross carmellose sodium, purified talc, magnesium stearate, gelatin, titanium dioxide (E171), erythrosine (E127) and red iron oxide (E172).

### **What Co-codamol Capsules look like and contents of the pack**

Co-codamol Capsules are red (cap) and white (body) coloured hard gelatin oblong capsules with no markings.

Co-codamol Capsules are available in packs of 30, 32 or 100 capsules. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mercury Pharmaceuticals Ltd.,  
Dashwood House, 69 Old Broad Street,  
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### **Manufacturer**

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