

## Package leaflet: Information for the user

# Codeine Phosphate Tablets

**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.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor, nurse or pharmacist.

### In this leaflet:

1. What Codeine Phosphate Tablets are and what they are used for
2. Before you take Codeine Phosphate Tablets
3. How Codeine Phosphate Tablets should be taken
4. Possible side effects
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## 1. What Codeine Phosphate Tablets are and what they are used for

This medicine has been prescribed for you to relieve pain, suppress coughs or treat diarrhoea. 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.

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. Before you take Codeine Phosphate Tablets

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 Codeine Phosphate Tablets 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 Phosphate Tablets should not be given if you:

- have ever had a reaction to or been told that you are allergic to codeine phosphate, any other opioid analgesic or any of the other ingredients in the tablets (see section 6)
- have been told you have a tumour of the adrenal gland near your kidney called phaeochromocytoma
- have severe problems with breathing
- are pregnant or breast-feeding
- have increased pressure on the brain, have just had a head injury or if you are unconscious
- are suffering from acute alcoholism
- are at risk from a blocked intestine
- have severe stomach cramps caused by a condition known as biliary colic
- are suffering from severe diarrhoea
- 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

### Speak to your doctor before you take Codeine Phosphate Tablets if you:

- are using drugs or have used drugs in the past as taking codeine phosphate for a long time can lead to addiction
- are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs) such as moclobemide, or phenelzine used in the treatment of depression
- suffer from asthma (your doctor may decide to administer Codeine Phosphate Tablets if your asthma is controlled. However, you should not be given this medicine if you are having an acute asthma attack)
- suffer from bronchitis (an inflammation of the lining of the tubes in the lungs, resulting in coughing spells accompanied by thick phlegm and breathlessness) or emphysema (a lung condition which leaves you struggling for breath)
- suffer from cor-pulmonale (a type of heart failure)

- are severely obese
- have a severely deformed spine
- are suffering from mental illness brought on by an infection
- have liver problems
- have kidney problems
- have problems with your bile duct
- suffer from an enlarged prostate gland (in men) or have difficulty passing urine
- have an under-active thyroid or adrenal gland
- have low blood pressure
- are in a state of severe shock
- are very run down
- have inflammatory bowel disease, such as Crohn's disease or ulcerative colitis or a blockage in the bowel muscles
- suffer from convulsions (fits)
- are a child or elderly
- are feeling weak and feeble
- have 'myasthenia gravis' (tiredness and weakness of some of your muscles e.g. eyes, mouth and throat muscles)
- are a poor metaboliser of codeine

If any of the above apply to you, speak to your doctor, nurse or pharmacist before you take Codeine Phosphate Tablets.

Contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 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.

### 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.

### Taking other medicines

It is very important that you inform your doctor if you are taking or have taken any other medicines, as some medicines may affect the way Codeine Phosphate Tablets work. In particular, tell your doctor if you are taking any of the following:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression. You must also tell your doctor if you have stopped taking any of these or related medicines in the last two weeks
- tricyclic antidepressants, which are used in the treatment of depression
- tranquillising drugs or sleeping tablets such as diazepam, nitrazepam and temazepam
- medicines used to treat mental illnesses, including schizophrenia (e.g. chlorpromazine, haloperidol)
- medicines used for diarrhoea (e.g. loperamide, kaolin)
- medicines which are used as premedication before operations and after heart attacks such as atropine
- anaesthetics, particularly general anaesthetics (used in surgery to numb pain)
- antihistamines such as benadryl (used to treat allergies e.g. hayfever)
- sodium oxybate (used to treat narcolepsy)
- medicines used to treat nausea and vomiting, such as metoclopramide or Domperidone
- mexiletine or quinidine, used to control heart rhythm
- cimetidine, used to treat stomach ulcers and indigestion
- ritonavir, used to treat HIV (a viral infection)

### Food and drink and Codeine Phosphate Tablets

You should not drink alcohol whilst you are taking Codeine Phosphate Tablets, as they will increase its effects. Alcohol may increase the sedative effects of codeine phosphate and make you very sleepy.

### Pregnancy and breast-feeding

You should not be given codeine if you are pregnant or think you might be pregnant unless you have discussed this with your doctor first. If you are given codeine during pregnancy and become dependent on it, there is a risk that the new-born baby may also be dependent and suffer from withdrawal symptoms following delivery. If you are given codeine during labour there is a risk that you could be sick and have breathing difficulties, or the baby could have difficulty starting breathing. Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

### Driving and using machines

You may feel drowsy and confused and you may develop blurred or double vision when you are taking Codeine Phosphate Tablets, so you should not drive or operate machinery. This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you.

It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain - go to <https://www.gov.uk/drug-driving-law>

## 3. How Codeine Phosphate Tablets should be given

Your prescriber should have discussed with you, how long the course of tablets 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 usual starting dose for adults and children aged 12 years or above for relief of mild to moderate pain is 30mg to 60mg every six hours, as needed.

The usual adult starting dose for diarrhoea is 30mg, three or four times daily. No more than 240mg should be taken in 24 hours. In all cases, dosage will be reduced for elderly. Codeine Phosphate tablets should not be taken by children below the age of 12 years due to the risk of severe breathing problems. Codeine Phosphate Tablets are not recommended for the treatment of diarrhoea in children. You may need a reduced dose if you have kidney or liver problems. You may also be given a reduced dose if you suffer from any of the conditions listed above in the section headed 'Speak to your doctor before you take Codeine Phosphate Tablets if you:' Your doctor will decide the dose that is best for you. Always follow your doctor's instructions completely. Also, follow any special instructions or warnings that appear on the label that the pharmacist has put on the package. If you do not understand or are in any doubt, ask your pharmacist.

Unless instructed differently, take your tablet(s) with a glass of water. If you have been given a blister pack, to obtain a tablet, press on the tablet from the blister (or bubble) pushing it through the foil. Do not remove the tablet from the blister until you are ready to take it.

**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.**

#### **If you miss a dose of Codeine Phosphate Tablets**

You should continue to take your medicine for as long as your doctor tells you to. If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER double the next dose to make up for the one missed. Do not stop taking the medicine without telling your doctor first.

#### **If you stop taking Codeine Phosphate Tablets**

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.

#### **Pregnancy**

Do not take Codeine Phosphate Tablets 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 Codeine Phosphate Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Codeine Phosphate Tablets while you are breastfeeding as codeine passes into breast milk and will affect your baby.

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

Like all medicines, codeine can cause side effects, but not everybody gets them. Tell your doctor or nurse immediately if you experience the following serious side effect:

- a severe allergic reaction (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing). If you suffer such a reaction, you should not be given any more codeine. Your doctor will decide on the appropriate treatment for allergic reactions. Difficulty in breathing and physical and psychological dependence are possible serious side effects. It is possible that you could become dependent on codeine.

Side effects that are common include:

- drowsiness
- feeling sick or being sick
- constipation
- sweating

Apart from constipation, these side effects tend to disappear with time.

Side effects that are less common include:

- dizziness
- feeling faint on standing up
- small pupils (in the eye)
- blurred vision
- double vision or other changes in vision
- mental clouding or confusion
- mood changes such as depression and sadness
- feeling extremely happy for no particular reason
- imagining things (hallucinations)
- nightmares
- headache
- vertigo (a feeling of dizziness or being lightheaded)
- facial flushing
- difficulty breathing
- stomach cramps
- sweating
- dry mouth
- difficulty or pain in passing urine
- passing less urine than usual
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- palpitations (trembling, shaking, irregular heart beats)
- increased pressure within your head (raised intracranial pressure)
- hyperglycaemia (abnormally high levels of glucose in the blood)
- pancreatitis (inflammation of the pancreas)
- feeling unwell
- feeling tired
- hypothermia
- fever
- an enlarged spleen or swollen/enlarged lymph nodes
- anorexia
- uncontrolled muscle movements
- restlessness
- muscle rigidity
- slower or faster pulse
- skin rash
- wheals or itching
- reduced sexual drive or impotence after long term use

Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

#### **Drug Withdrawal**

When you stop taking Codeine Phosphate Tablets, 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 Codeine Phosphate Tablets, 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 national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Malta:

ADR Reporting, Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Codeine Phosphate Tablets**

Do not store above 25°C. Store in the original package or container in which they were given to you in order to protect from light. Do not transfer them to another container.

#### **Keep out of the sight and reach of children.**

Do not use Codeine Phosphate Tablets if the tablets show signs of discolouration.

Do not use Codeine Phosphate Tablets after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month. REMEMBER this medicine is for YOU only. Never give it to anyone else. It may harm them, even if the symptoms are the same as yours. Unless your doctor tells you to, do not keep tablets that you no longer need. Give them back to the pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Further information**

#### **What Codeine Phosphate Tablets contain**

The active ingredient in Codeine Phosphate Tablets is Codeine Phosphate. The tablets contain 15mg or 30mg of the active ingredient. Other ingredients are lactose, acacia spray-dried, maize starch, magnesium stearate and stearic acid.

#### **What Codeine Phosphate Tablets looks like and contents of the pack**

Codeine Phosphate 15mg Tablets are white circular tablets marked C15 on one face and CP on the other.

Codeine Phosphate 30mg Tablets are white circular tablets marked C30 on one face and CP on the other.

Codeine Phosphate 15mg and 30mg Tablets are available in blister packs of 28, 30, 56, 60, 84, 90 and 100 tablets.

Codeine Phosphate 15 mg Tablets are available in 28, 30, 56, 60, 84, 90, 100, 250 and 500 tablets in polypropylene/polyethylene containers.

Codeine Phosphate 30 mg Tablets are available in 28, 30, 56, 60, 84, 90, 100, 250, 500, 1,000 and 10,000 tablets in polypropylene/polyethylene containers.

Codeine Phosphate 30 mg Tablets are available in 100 tablets in amber glass bottles.

Not all strengths and pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder in UK: Wockhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK.

Marketing Authorisation Holder in Malta: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

**Manufacturer:** CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Codeine Phosphate 15mg Tablets	29831/0048
Codeine Phosphate 30mg Tablets	29831/0049

This is a service provided by the Royal National Institute of Blind

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