

Package leaflet: Information for the user

Codeine Phosphate Tablets BP 15 mg Codeine Phosphate Tablets BP 30 mg

Codeine phosphate

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.

What is in this leaflet

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

This medicine contains codeine phosphate which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Codeine Phosphate Tablets are and what they are used for

This medicine has been prescribed for adults for relief of pain, relief of coughing and symptomatic relief of prolonged loose stools (diarrhoea) and for 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.

It contains codeine phosphate 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 can be used on its own or in combination with other painkillers such as paracetamol.

2. What you need to know before you take Codeine Phosphate Tablets

Do not take Codeine Phosphate Tablets if you:

- are allergic to codeine phosphate or any of the other ingredients of this medicine (listed in section 6)
- have suffered a head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- have liver failure
- have severe breathing problems or other chronic lung disease
- are having an asthma attack
- suffer with acute alcoholism
- have diarrhoea associated with either severe inflammation of the bowel or poisoning
- are at risk of blocked intestines
- are under 12 years old
- know that you metabolise very rapidly codeine into morphine
- are breastfeeding.

Do not use Codeine Phosphate Tablets 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.

Adolescents older than 12 years of age

Codeine is not recommended in adolescents with compromised respiratory function for the treatment of cough and/or cold.

Warnings and precautions

Talk to your doctor or pharmacist 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 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
- 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
- have suffered from alcoholism, drug abuse or dependence or mental illness, irregular heartbeat or convulsions
- have recently undergone surgery of gastro-intestinal tract or urinary system.
- have been diagnosed as suffering from any of the following:
 - low blood pressure or are in shock
 - deficiency in the activity of the thyroid gland
 - enlarged prostate
 - acute abdominal conditions
 - gallstones or gall bladder disease
 - severe weakness of muscles
- have liver or kidney problems
- have asthma or breathing problems
- have problems with your adrenal glands (such as Addison's disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)

- have inflammatory bowel disease including severe bloody diarrhoea (pseudomembranous colitis)
- are elderly or frail.
- experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Other important warnings:

taking a painkiller for headaches too often or for too long can make them worse.
Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Codeine Phosphate tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

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 Codeine Phosphate tablets 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 Codeine Phosphate tablets, 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 cough or 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 Codeine Phosphate tablets).

Sleep-related breathing disorders

Codeine Phosphate tablets 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.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cough. 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 or relieve their cough. 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.

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.

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 Codeine Phosphate Tablets

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

Codeine is known to interfere with some medicines. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs (e.g. linezolid, moclobemide, selegiline etc) used to treat depression (refer to “Warnings and precautions” in section 2 above)
- hypnotics and alcohol
- other anti-diarrhoeal agents (e.g. loperamide, kaolin)
- anti-hypertensives (medicines used to control high blood pressure)
- cimetidine (to treat stomach ulcers)
- tricyclic antidepressants (eg amitriptyline)
- ciprofloxacin (antibacterial medicine)
- metoclopramide or domperidone (to prevent sickness)
- mexiletine or quinidine (to treat irregular heartbeats)
- antiviral medicines such as ritonavir
- medicines to treat allergies (antihistamines) that can cause drowsiness
- atropine (anticholinergic medicines)
- medicines which affect the nervous system such as chlorpromazine, diazepam, temazepam
- anaesthetics
- opioid antagonists (buprenorphine, naltrexone, naloxone).

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

Concomitant use of Codeine Phosphate Tablets 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 Codeine Phosphate 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.

Codeine Phosphate Tablets with food, drink and alcohol

Do not drink alcohol whilst taking Codeine Phosphate Tablets. Alcohol may increase the sedative effects of Codeine Phosphate Tablets and make you very sleepy.

You can take the tablets regardless of food intake.

Pregnancy, breast-feeding and fertility

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 phosphate passes into breast milk and will affect your baby. Some women who are at increased risk of developing side effects at any dose may have higher levels of codeine in their breast milk.

If any of the following side effects develop in you or your baby stop taking this medicine and seek immediate medical advice; feeling sick, being sick, constipation, poor appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

Driving and using machines

Do not drive or operate machinery because you may suffer from confusion, drowsiness, hallucinations (seeing, feeling or hearing things that are not there), blurred or double vision, fits or dizziness. This can affect driving or the operation of 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.

Codeine Phosphate Tablets contain lactose and sodium

This medicine contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Codeine Phosphate Tablets contain less than 1 mmol sodium (23 mg) per maximum daily dose, that is to say essentially 'sodium-free'.

3. How to take Codeine Phosphate Tablets

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.

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Codeine Phosphate tablets, 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 Codeine Phosphate tablets).

The recommended dose is:

For the relief of pain

Adults and children over 12 years: 30-60 mg every four hours, when necessary to a maximum of 240 mg daily.

For the relief of coughing

Adults: 15-30 mg three or four times daily.

For the treatment of prolonged diarrhoea

Adults: 15-60 mg every four to six hours. Do not take more than 240 mg in 24 hours.

A lower dosage may be needed if you are an older person who may have liver or kidney problems.

The 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.

Codeine Phosphate tablets should be used for the shortest duration necessary to relieve symptoms.

Use in children and adolescents

Children below the age of 12 years

Codeine Phosphate Tablets should not be taken by children below the age of 12 years due to the risk of severe breathing problems.

Children aged 12 years to 18 years

In children and adolescents between 12 years and 18 years who have problems with their breathing, codeine is not recommended as this population may be more susceptible to breathing problems due to codeine.

Swallow these tablets with water.

If you take more Codeine Phosphate Tablets than you should

If you take too many tablets, you may have symptoms such as feeling or being sick, depression, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate. Contact your doctor or pharmacist at once for advice.

If you forget to take Codeine Phosphate Tablets

If you forget to take a dose take it as soon as you remember and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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.

Prolonged use can lead to tolerance and dependence on the medicine. Taking codeine regularly for a long time can be habit forming, which might cause you to feel restless and irritable when you stop the tablets. Your doctor will stop your tablets gradually to avoid you having 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, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If the following happens, stop taking Codeine Phosphate Tablets and tell your doctor immediately or contact the casualty department at your nearest hospital

- allergic reactions (itch, hives, skin rash, redness, increase sweating, flushed face, difficulty breathing)
- increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes)
- fits (convulsions)

Other side effects

- confusion, dizziness, drowsiness, tiredness, changes in mood, nightmares, mental depression
- restlessness/excitement
- headache
- hallucinations (seeing, feeling or hearing things that are not there)

- feeling sick (nausea), constipation, vomiting, dry mouth
- abdominal pain (may be caused by spasm of the bile ducts)
- low body temperature
- blurred or double vision, extremely small pupils
- palpitations, low blood pressure, low blood pressure on standing, slow or fast heart beat
- malaise (general discomfort)
- pain and difficulty in passing water and a less frequent need to do so
- uncontrolled muscle movements and rigidity
- decrease in sex drive.

Tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)

Unknown frequency:

- Dependence and addiction (see section “How do I know if I am addicted?”).
- 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.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Codeine Phosphate Tablets

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.

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 label, carton and blister after “EXP”. The expiry date refers to the last day of that month.

Store below 25°C. Store the tablets in the original packaging. Do not put them in another container. For container packaging replace the cap securely after use.

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 Codeine Phosphate Tablets contains

- The active substance is codeine phosphate. Each tablet contains 15 mg or 30 mg of codeine phosphate.
- The other ingredients are lactose monohydrate, magnesium stearate, sodium starch glycolate and starch, pregelatinised.

What Codeine Phosphate Tablets look like and contents of the pack

Codeine Phosphate 15 mg tablets are white to off white, circular normal biconvex tablets embossed with R114.

Codeine Phosphate 30 mg tablets are white to off white, circular normal biconvex tablets embossed with R115.

The tablets are available in 15 mg and 30 mg strengths and in containers of 1000, 500, 100, 90, 80, 70, 60, 50, 40, 30, 20 and 10 tablets and in blister strips of 100, 90, 80, 70, 60, 50, 40, 30, 28, 20 and 10 tablets.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

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