

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

Codeine Phosphate Tablets contain codeine phosphate. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

Codeine Phosphate Tablets are used in adults for:

- relief of pain
- relief of coughing
- symptomatic relief of prolonged loose stools (diarrhoea)

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. 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 Codeine Phosphate Tablets if 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.
- 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

Other important warnings:

- 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.

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.

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)
- phenobarbitone (medicine used for control of fits)
- potassium iodide
- 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).

Laboratory test results may also be affected.

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 use this medicine if you are pregnant. Do not take codeine while you are breastfeeding.

Codeine and morphine passes into breast milk.

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

Ask your doctor or pharmacist for advice before taking any medicine.

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 'sodium-free'.

3. How to take Codeine Phosphate 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 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.

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

If you stop taking the tablets you may develop the following withdrawal symptoms tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure, restlessness, irritability, anxiety, depression, loss of appetite, loose stool, excessive tears, runny nose, sneezing, yawning, hair standing on ends, widening of the pupil, weakness, fever, muscle cramps, dehydration.

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)

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

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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