

Codeine Phosphate 15mg, 30mg and 60mg Tablets

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

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

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. The tablets can be used on their own or in combination with other pain killers such as paracetamol. Codeine Phosphate Tablets are used for the relief of:

- mild to 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 pain killers such as paracetamol or ibuprofen alone- symptoms of a dry cough or diarrhoea.

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

Do not take Codeine Phosphate Tablets:

- if you are **allergic** (hypersensitive) to codeine or other opioids, or any of the ingredients in the tablet (listed in section 6)
- if you have **difficulty breathing**, or other chronic lung disease
- if you have suffered **head injury** or **raised pressure** in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- if you are having an **asthma attack**
- if you have **liver failure**
- if you are at risk of **blocked intestines**
- if you suffer with **alcoholism**
- if you are **under 12 years old**
- 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
- if you know that you **metabolise very rapidly codeine into morphine**
- if you are **breast-feeding**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Codeine Phosphate Tablets if you:

- have **liver** or **kidney** problems
- have diseased adrenal glands (**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)

- have **gall bladder disease** or **gall stones**
- have recently had **surgery** on your gastro-intestinal tract or urinary system
- have an **enlarged prostate** gland and have **difficulty urinating** and are **male**
- have **epilepsy**
- are **elderly** or **frail**
- suffer with **asthma** or **breathing problems**
- have an **underactive thyroid** gland
- have muscle weakness (**myasthenia gravis**)
- have **low blood pressure** or are in **shock**
- have suffered from **alcoholism, drug abuse** or **dependence**.

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.
- Adolescents older than 12 years of age: Codeine is not recommended in adolescents with compromised respiratory function for the treatment of cough.

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.

Other medicines and Codeine Phosphate Tablets

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines, including medicines obtained without a prescription or might take any other medicines. Especially:

- medicines to treat depression such as Monoamine Oxidase Inhibitors (MAOIs eg moclobemide, linezolid, selegiline. Avoid Codeine Phosphate Tablets for 2 weeks after stopping the MAOI) or tricyclics (eg amitriptyline)
- ciprofloxacin (antibacterial medicine)
- metoclopramide or domperidone (to prevent sickness)
- mexiletine or quinidine (to treat irregular heartbeats)
- loperamide or kaolin (to treat diarrhoea)
- cimetidine (to treat stomach ulcers)
- medicines used to treat high blood pressure
- antiviral medicines such as ritonavir
- medicines to treat allergies (antihistamines) that can cause drowsiness
- anticholinergic medicines like atropine
- medicines which affect the nervous system such as chlorpromazine, diazepam, temazepam
- anaesthetics
- opioid antagonists (buprenorphine, naltrexone, naloxone).

Codeine Phosphate Tablets with food, drink and alcohol

Do not drink alcohol while taking Codeine Phosphate Tablets.

Swallow the tablets with **water**.

Pregnancy and breast-feeding

Do not take Codeine Phosphate Tablets during pregnancy unless advised by your doctor. Regular use during pregnancy may cause withdrawal symptoms in newborn babies. 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.

Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk. Usually it is safe to take Codeine Phosphate Tablets while breast-feeding as the level of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, 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

Codeine Phosphate Tablets may make you feel drowsy, confused or dizzy, cause fits, blurred or double vision or to see things that are not there. Make sure you are not affected before you drive or operate 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

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3 How to take Codeine Phosphate Tablets

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

Do not drink alcohol whilst taking Codeine Phosphate Tablets. Swallow the tablets with **water**.

Codeine Phosphate Tablets are normally used only for short-term relief of symptoms, take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

Doses:

Adults:

For pain relief – 30 - 60mg every four hours up to a maximum of 240mg a day.

For diarrhoea – 15 - 60mg three to four times a day.

For cough – 15 - 30mg three to four times a day.

Elderly patients with liver or kidney damage:

Your doctor may give you a smaller dose. If you are elderly, it is particularly important to take this medicine exactly as directed by the doctor.

Use in children and adolescents:

Children aged 12 years or above:

For pain relief - 30 - 60mg every 6 hours, as needed. **Do not** take more than 240mg in 24 hours.

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.

Codeine Phosphate Tablets should not be used for pain relief in children aged 12 years or above after removal of tonsils or adenoids (see **Warnings and Precautions**). Talk to your doctor before taking this medicine if this applies to you.

For diarrhoea – 15 - 60mg three to four times a day.

For cough - 15 - 30mg three to four times a day. Codeine Phosphate Tablets are not recommended for treatment of cough in children aged 12 years or above if they have breathing problems. Talk to your doctor before taking this medicine if this applies to you.

Children under 12 years:

Codeine Phosphate Tablets are **not** recommended for use in children under 12 years. Codeine Phosphate Tablets **must not** be taken by children below the age of 12 years for treatment of cough, due to the risk of severe breathing problems.

If you take more Codeine Phosphate Tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate.

If you forget to take Codeine Phosphate Tablets

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

If you stop taking Codeine Phosphate Tablets

If you stop taking Codeine Phosphate 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, anorexia, diarrhoea, excessive tears, runny nose, sneezing, yawning, hair standing on ends, widening of the pupil, weakness, fever, muscle cramps, dehydration.

4 Possible side effects

Like all medicines, Codeine Phosphate Tablets can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Allergic Reactions** - skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face
- **Gastrointestinal system** - constipation, feeling or being sick, dry mouth, abdominal pain (may be caused by spasm of the bile ducts)
- **Heart** - slow or fast heart rate, palpitations, low blood pressure, low blood pressure on standing
- **Urinary system** - pain and difficulty in passing urine and a less frequent need to do so
- **Nervous system** - drowsiness, malaise, tiredness, dizziness, 'spinning' sensation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, 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)
- **Psychiatric effects** - mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, nightmares, confusion
- **Eyes** - blurred or double vision, extremely small pupils
- **Others** - muscle stiffness, decrease in sex drive, difficulty breathing, low body temperature.

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 at: www.hra.gov.uk/yellowcard.

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

5 How to store Codeine Phosphate Tablets

Keep out of the sight and reach of children.

Store below 25°C in a dry place, protected from light.

Do not use Codeine Phosphate Tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 Codeine Phosphate Tablets contain

- The active substance (the ingredient that makes the tablets work) is codeine phosphate. Each tablet contains either 15mg, 30mg or 60mg of the active ingredient.
- The other ingredients are lactose, magnesium stearate, pregelatinised maize starch, maize starch, stearic acid.

What Codeine Phosphate Tablets look like and contents of the pack

Codeine Phosphate Tablets are white, uncoated tablets.

Pack sizes are 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in September 2016.