

CODEINE PHOSPHATE 15 mg, 30 mg AND 60 mg TABLETS

Package leaflet: Information for the user

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.

What is in this leaflet

1. What Codeine Phosphate is and what it is used for
2. What you need to know before you take Codeine Phosphate
3. How to take Codeine Phosphate
4. Possible side effects
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1 What Codeine Phosphate is and what it is used for

This medicine has been prescribed for you to:

- treat mild to moderate pain
- suppress a troublesome cough
- treat diarrhoea.

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, and how to do this safely.

Your tablets are called Codeine Phosphate Tablets. Codeine Phosphate Tablets contain the active substance codeine. Codeine Phosphate Tablets 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.

If you are travelling abroad, you may require a letter from your doctor explaining why you need to take these tablets.

2 What you need to know before you take Codeine Phosphate

Do not take Codeine Phosphate:

- if you are allergic to Codeine Phosphate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from liver disease
- if you suffer from alcoholism
- if you suffer from breathing difficulties or are having an asthma attack, since the symptoms of morphine toxicity may be worse in such patients
- if you suffer from colitis (inflammation of the colon) or at risk of a blockage in your gut
- if you have recently had a head injury, or you suffer from raised pressure in your head (this may cause vomiting, headache and changes in behaviour)
- if you metabolise very rapidly codeine into morphine
- if you are breast-feeding
- 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.

Warnings and precautions

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 Codeine phosphate 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.

DO NOT take Codeine Phosphate for longer than directed by your prescriber

Taking Codeine Phosphate as 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.

Talk to your doctor before you start to take this medicine

- if you have suffered from alcoholism, drug abuse or dependence
- if you have diarrhoea which is known to be caused by an infection
- if you have low blood pressure
- if you have prostate problems
- if you have problems with your thyroid gland
- if you have problems with your kidneys
- if you have liver impairment
- if you suffer from asthma
- if you suffer from chronic bronchitis
- if you suffer from fits.

Children and adolescents

Codeine Phosphate should not be used in children below the age of 12 years because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine.

Adolescents older than 12 years of age

Codeine Phosphate is not recommended for use in adolescents aged 12 years to 18 years with compromised respiratory function for the treatment of cough.

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:

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

Do not take Codeine Phosphate:

- if you are taking or have recently stopped taking (within the last 2 weeks) monoamine oxidase inhibitors (MAOI) for the treatment of depression.

Talk to your doctor if you are taking any of the following:

- metoclopramide, domperidone, flecainide or mexiletine
- antipsychotics (medicines used to treat mental disorders) e.g. chlorpromazine
- ciprofloxacin
- ritonavir or cimetidine
- antidepressants.

Concomitant use of Codeine Phosphate 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 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 with food and drink

- DO NOT drink alcohol with Codeine Phosphate, as it may affect you more than usual.

Pregnancy and breast-feeding

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

Driving and using machines

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 contains lactose

- Patients who are intolerant to lactose should note that Codeine Phosphate tablets contain a small amount of lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Codeine Phosphate

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

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.

Do not take a higher dose or more often than the doctor has told you.

The recommended dose is:

Adults

Pain relief

30 – 60 mg every four hours when necessary, up to a maximum of 240 mg in 24 hours.

Treatment of diarrhoea

30 mg three to four times daily.

Treatment of cough

15 - 30 mg three to four times daily.

Use in children and adolescents

Children aged 12 years to 18 years

The recommended codeine dose for children 12 years and older should be up to a maximum dose of codeine of 240 mg daily.

Analgesic use

30 - 60 mg every 6 hours as needed. The dose is based on the body weight (0.5 - 1 mg/kg).

For cough

The dose is based on bodyweight 1 - 2 mg/kg daily in 4 to 6 divided doses.

The use of cough suppressants containing codeine is not generally recommended in children.

Anti-diarrhoeal use

Not recommended.

Children aged under 12 years:

Codeine Phosphate is not suitable for use in children under 12 years of age, due to the risk of severe breathing problems.

The Elderly, or patients with liver or kidney problems:

- A reduced adult dosage, as prescribed by your doctor.

The tablets should be swallowed preferably with a drink of water.

The medicine should not be taken for more than 3 days and if no effective pain relief is achieved the patients/carers should be advised to seek the views of a physician.

If you take more Codeine Phosphate than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause breathing problems, nausea (feeling sick) and vomiting. An overdose can lead to death. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Codeine Phosphate

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Codeine Phosphate

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, Codeine Phosphate can cause side effects, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

The following side effects have been reported:

- Allergic reactions: rashes, itching, nettle rash, breathing difficulties, increased sweating reddening or flushing of the face
- Gastrointestinal system: constipation, abdominal pain (may be caused by spasm of the bile ducts), nausea (feeling sick), vomiting (being sick), dry mouth, pancreatitis (inflammation of pancreas, which causes severe pain in the abdomen and back)
- Heart: change in heart rate (either faster or slower), palpitations, low blood pressure (dizziness or fainting)
- Urinary system: pain and difficulty in passing urine and a less frequent need to do so
- Nervous system: drowsiness, a general feeling of restlessness, uneasiness or of being unwell (malaise), tiredness, dizziness, a sensation that your surroundings are spinning either up and down or from side to side, 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 (hearing or seeing things that are not real), restlessness, excitation, nightmares, confusion, dependence and addiction (see section "How do I know if I am addicted?").
- Eyes: blurred or double vision, pinpoint pupils.
- Others: muscle stiffness, low body temperature, reduced sex drive, impotence, difficulty breathing, impaction of the faeces may occur, particularly in elderly patients, which could lead to incontinence, unexplained diarrhoea, abdominal pain and in rare cases, obstruction of the intestine.

Drug Withdrawal

When you stop taking Codeine Phosphate, 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, 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

Keep this medicine out of the sight and reach of children.

These tablets should be stored in a dry place below 25°C and protected from light in the package or container supplied. Do not transfer them to another container.

Do not use Codeine Phosphate after the expiry date that is stated on the outer packaging. 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 protect the environment.

6 Contents of the pack and other information

What Codeine Phosphate tablets contain:

- The active ingredient is codeine phosphate, either 15 mg, 30 mg or 60 mg.
- The other ingredients are dextrin, lactose, and magnesium stearate.

What Codeine Phosphate tablets look like and contents of the pack:

- Codeine Phosphate tablets are white to off-white, biconvex tablets. The tablets are marked as follows:
 - 15 mg tablets: 'APS' on one side and '15/0507' on the reverse, or 'APS' over '0507' on one side and plain on the reverse.
 - 30 mg tablets: 'APS' on one side and '30/0508' on the reverse, or 'APS' over '0508' on one side and plain on the reverse.
 - 60 mg tablets: "APS" on one side and "60/0509" on the reverse, or "APS" over "0509" on one side and plain on the reverse.
- The tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG.
Company Responsible for Manufacture: TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13, Debrecen, H-4042, Hungary.

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