PACKAGE LEAFLET: INFORMATION FOR THE USER

Codeine Phosphate 15mg Tablets BP
Codeine Phosphate 30mg Tablets BP
Codeine Phosphate 60mg Tablets BP
(Codeine Phosphate)

This medicine contains Codeine Phosphate 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 or nurse. This includes any possible side effects not listed in this leaflet.

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 medicine has been prescribed for you to relieve pain, suppress coughs and treat diarrhoea.
It contains the 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. 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 for longer than directed by your prescriber**
- **taking codeine regularly for a long time can lead to addiction, which might make you 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 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 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 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 oxadise 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)
- have a severely deformed spine
- have liver problems
- have problems with your bile duct
- have an under-active thyroid or adrenal gland
- are in a state of severe shock difficulty passing urine
- have inflammatory bowel disease, such as Crohn's disease or ulcerative colitis or a blockage in the bowel muscles
- are a child or elderly
- have 'myasthenia gravis' (tiredness and weakness of some of your muscles e.g. eyes, mouth and throat muscles)
- are a poor metaboliser of codeine
- are severely obese
- are suffering from mental illness brought on by an infection
- have kidney problems
- suffer from an enlarged prostate gland (in men) or have
- have low blood pressure
- are very run down
- suffer from convulsions (fits)
- are feeling weak and feeble
- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

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

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.

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.

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 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 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, 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 pain or cough.
- 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).

Sleep-related breathing disorders
Codeine Phosphate 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.

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
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, nitrazepamand 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)
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

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
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, breast-feeding and fertility
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.

N24052

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
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

Important information about some of the ingredients of Codeine Phosphate Tablets:
These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars then do not take these tablets until you have consulted your doctor.

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.

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

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.

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. The recommended oral dose is:

Adults
For relief of mild to moderate pain, 30mg to 60mg every six hours as needed.. For diarrhoea, 30mg three or four times daily.

For a dry and painful cough, 15 to 30mg three or four times a day. No more than 240mg should be taken in 24 hours.

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.

Adolescents older than 12 years of age
The recommended starting dose for children aged 12 years or above for relief of mild to moderate pain is 30mg to 60mg every six hours, as needed.

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.

The Elderly: in all cases the dosage should be reduced.

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

If you take more Codeine Phosphate Tablets than you should

If you or someone else swallow several of these tablets together, contact your doctor or nearest hospital emergency department immediately. Always take any tablets left over with you, this leaflet and also the box, as this will allow easier identification of the tablets.

Taking too much medicines is called an overdose, whether it's internal or not. This can be very serious and may cause death. Some of the signs of an overdose include
- Confusion or hallucinations
- Slurred speech
- Lips or fingernails are blue or purple
- Poor coordination or balance
- Unresponsive or unconscious
- Heavy or unusual snoring
- Difficulty breathing or no breathing
- Very small pupils in the eyes

Your family, friends, and carers should know these signs so they can take immediate action.

If you think that you or someone else has taken too much of their opioid medicine, dial 999 immediately. If you forget to take 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 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.

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. 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
- constipation
- feeling sick or being sick
- sweating

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

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?
Addiction can happen gradually, It 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. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

If your pain is becoming difficult to manage, talk to your doctor. Your body may have stopped sensing the pain-relieving effect of your opioid. This is called 'opioid tolerance'. It could be an early warning sign that you are at risk of becoming addicted.

Signs that you may be addicted to opioids include:
- Craving of the medicine
- Feeling that you need to take more medicine than prescribed or as instructed on the pack, even though the medicine is causing unwanted effects on your overall health (for example, some of the withdrawal side effects in the next section)
- Feeling that you need to take additional medicines containing opioids or other pain relief medicines to achieve the same relief
- Taking opioid medicines for reasons other than pain relief; for instance, to 'stay calm' or 'help you sleep'
- Experiencing withdrawal side effects when you stop taking the medicine suddenly (see below).

If you notice any of the above, talk to your doctor or a pharmacist.
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.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 store above 25°C. Store in the original package and keep containers tightly closed.
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. 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.
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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Codeine Phosphate Tablets contains
The **active** substance is Codeine Phosphate.
The **other** ingredients are lactose monohydrate, acacia, maize starch, magnesium stearate and stearic acid. (see Section 2 'Important information about some of the ingredients of Codeine Phosphate Tablets').

What Codeine Phosphate Tablets looks like and contents of the pack
Codeine Phosphate Tablets 15mg are white, circular tablets marked C15 on one face.
Codeine Phosphate Tablets 30mg are white, circular biconvex tablets
Codeine Phosphate Tablets 60mg are white, circular tablets marked C60 on one face.
Codeine Phosphate Tablets are available in container packs of 28,30,56,60,84,90,100, 250 and 500 tablets. They are also available in blister packs of 28, 30, 56, 60, 84,90 and 100 tablets (Not all pack sizes may be marketed).

Marketing Authorisation Holder
Milpharm Limited,
1 Roundwood Avenue,
Stockley Park,
Uxbridge,
UB11 1AF
United Kingdom

Manufacturer
Generis Farmaceutica S.A.
Rua Joao De Deus, N° 19,
Venda Nova,
2700-487 Amadora

This leaflet was last revised in 01/2026.

Ref: Ver 1.0

N24052

2mm 8mm 2mm 75mm 12mm 600mm