

Format: 180X600mm | Weight: 50gr

SENTIDO DE LEITURA

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Codeine Phosphate 15mg Tablets BP**  
**Codeine Phosphate 30mg Tablets BP**  
**Codeine Phosphate 60mg Tablets BP**  
(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 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 product contains codeine. 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 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. These tablets are used to relieve pain, suppress coughs and treat diarrhoea.

**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 pheochromocytoma
- 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 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 oxidase 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)
- are severely obese
- have a severely deformed spine
- are suffering from mental illness brought on by an infection
- have liver problems
- have kidney problems
- have problems with your bile duct
- suffer from an enlarged prostate gland (in men) or have difficulty passing urine
- have an under-active thyroid or adrenal gland
- have low blood pressure
- are in a state of severe shock
- are very run down
- have inflammatory bowel disease, such as Crohn's disease or ulcerative colitis or a blockage in the bowel
- suffer from convulsions (fits)
- are a child or elderly
- are feeling weak and feeble
- have 'myasthenia gravis' (tiredness and weakness of some muscles e.g. eyes, mouth and throat muscles)
- are a poor metaboliser of codeine

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

Contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**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.

**Warnings and precautions**

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effect 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.

**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, nitrazepam and 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)

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.

**Taking 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**

You should not be given codeine if you are pregnant or think you might be pregnant unless you have discussed this with your doctor first. If you are given codeine during pregnancy and become dependent on it, there is a risk that the new-born baby may also be dependent and suffer from withdrawal symptoms following delivery. If you are given codeine during labour there is a risk that you could be sick and have breathing difficulties, or the baby could have difficulty starting breathing. Do not take codeine while you are breastfeeding. Codeine and morphine pass into breast milk.

**Driving and using machines**

Codeine Phosphate tablets may cause drowsiness so you should avoid driving or operating machinery if affected.

**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 Codeine Phosphate Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Unless instructed differently, take your tablet(s) with a glass of water. The usual oral dose is:

180mm

Artwork Same Size  
Size : 180 x 600 mm

05 10 18

2mm 8mm 2mm

12mm

75mm

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**Adults**  
For relief of mild to moderate pain, 30mg to 60mg every six hours. 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.

**Adolescents older than 12 years of age**  
Codeine phosphate tablets are not recommended in adolescents with compromised respiratory function for the treatment of cough.

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

**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.

**If you forget to take Codeine Phosphate Tablets**  
If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Codeine Phosphate Tablets**  
You should always check with your doctor before the treatment is stopped. It is possible that you could become dependent on codeine and have withdrawal symptoms if it is stopped suddenly. This is more likely if you have a tendency for drug abuse or if you become dependent on Codeine Phosphate Tablets.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, codeine can cause side effects, but 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
- feeling sick or being sick
- constipation
- sweating

Apart from constipation, these side effects tend to disappear with time. Side effects that are less common include:

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

**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](http://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.  
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 and CP on the other. Codeine Phosphate Tablets 30mg are white, circular biconvex tablets  
Codeine Phosphate Tablets 60mg are white, circular tablets marked C60 on one face and CP on the other. 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).

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