

PACKAGE LEAFLET: INFORMATION FOR THE USER

CODEINE PHOSPHATE TABLETS

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
 - This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
 - If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.



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1. WHAT CODEINE PHOSPHATE TABLETS ARE AND WHAT THEY ARE USED FOR

Codeine phosphate belongs to a group of medicines known as opioid analgesics, which are used to relieve pain, suppress coughs and treat diarrhoea.

2. 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

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.

Taking other medicines

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)

Food and drink and Codeine Phosphate Tablets

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 and breast-feeding

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. Usually it is safe to take Codeine Phosphate Tablets while breast-feeding as the levels 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 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, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping longer than normal, and shallow or slow breathing.

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.

3. HOW CODEINE PHOSPHATE TABLETS SHOULD BE GIVEN

The usual adult starting dose for relief of mild to moderate pain is 30mg to 60mg every four hours when necessary. The usual adult starting dose for diarrhoea is 30mg, three or four times daily. No more than 240mg should be taken in 24 hours. In all cases, dosage will be reduced for elderly. Codeine Phosphate 30mg and 60mg Tablets are not recommended for children under the age of 12 years.

Codeine Phosphate 15mg Tablets are not recommended for the treatment of diarrhoea in children. 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.

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.

If you miss a dose of 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 stop taking the medicine without telling your doctor first.

If treatment with Codeine Phosphate Tablets is stopped

You should always check with your doctor before the treatment is stopped. It is possible that you could be come 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 light-headed)
- facial flushing
- difficulty breathing
- stomach cramps
- sweating
- dry mouth
- difficulty or pain in passing urine
- passing more or 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

It is important to tell your doctor, pharmacist or nurse if you suffer from any of these or any other undesirable effects which are not listed above.

5. HOW TO STORE CODEINE PHOSPHATE TABLETS

Do not store above 25°C. Store in the original package or container in which they were given to you in order to protect from light. Do not transfer them to another container.

Keep out of the reach and sight of children.

Do not use Codeine Phosphate Tablets if the tablets show signs of discolouration.

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. FURTHER INFORMATION

What Codeine Phosphate Tablets contain

The active ingredient in Codeine Phosphate Tablets is Codeine Phosphate. The tablets contain 15mg, 30mg or 60mg of the active ingredient.

Other ingredients are lactose, acacia spray-dried, maize starch, magnesium stearate and stearic acid.

What Codeine Phosphate Tablets looks like and contents of the pack

Codeine Phosphate 15mg Tablets are white circular tablets marked C15 on one face and CP on the other.

Codeine Phosphate 30mg Tablets are white circular tablets marked C30 on one face and CP on the other.

Codeine Phosphate 60mg Tablets are white circular tablets marked C60 on one face and CP on the other.

Codeine Phosphate 15mg, 30mg and 60mg Tablets are available in blister packs of 28, 30 and 100 tablets.

Not all strengths and pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Codeine Phosphate 15mg Tablets	29831/0048
Codeine Phosphate 30mg Tablets	29831/0049
Codeine Phosphate 60mg Tablets	29831/0050

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