



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

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CODEINE PHOSPHATE TABLETS

Do not take Codeine Phosphate Tablets:

- If you are under 12 years old.
- If you are allergic to Codeine Phosphate or to any of the other ingredients of Codeine Phosphate tablets.
- If you know that you metabolise very rapidly codeine into morphine.
- If you are breastfeeding.
- If you have liver disease.

Adolescents older than 12 years of age

Codeine phosphate tablets is not recommended in adolescents with compromised respiratory function for the treatment of cough

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.

Take special care with Codeine Phosphate Tablets:

Please tell your doctor before you start to take your tablets:

- If you have had a drug addiction.
- If you have liver or kidney problems.

Other Medicines and Codeine Phosphate Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those medicines obtained without a prescription.

In particular tell your doctor if you are taking:

- Drugs used to prevent you feeling sick or being sick e.g. *metoclopramide* or *domperidone*.
- Drugs used to regularise heart rhythm e.g. *flecainide* and *mexiletine*
- Sleeping tablets, sedatives, tricyclic antidepressants or phenothiazine tranquilisers (you may feel more sleepy if you take these medicines)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

Taking Codeine Phosphate Tablets with food and drink

You should avoid alcohol while taking these tablets.

Pregnancy, breast-feeding and fertility

If you are pregnant or planning to become pregnant then consult your doctor or pharmacist before taking these tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take codeine phosphate tablets while you are breast feeding. Codeine and morphine passes in to 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:

Adults

For relief of mild to moderate pain, 30mg to 60mg every four 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

Do not stop taking this medicine without telling your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Codeine Phosphate Tablets may cause side effects in some patients particularly when treatment is first started.

If you develop an **allergic (hypersensitive) reaction** e.g. skin rash or itching, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing, then stop taking Codeine Phosphate Tablets and tell your doctor immediately.

- Usual side effects are dizziness, feeling sick, constipation and sweating.
- Unusual bruising, or infections such as sore throats – this may be a sign of very rare changes in the blood

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

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 the tablets after the expiry date is stated on the label.

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 tablets marked C30 on one face and CP on the other.

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).

Marketing Authorisation Holder

Aurobindo Pharma Limited,
Ares, Odyssey Business Park,
West End Road,
South Ruislip HA4 6QD,
United Kingdom

Manufacturer

CP Pharmaceuticals Limited,
Ash Road North, Wrexham Industrial Estate,
Wrexham, LL13 9UF, United Kingdom

This leaflet was last approved in 07/2015.