Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets

Read all of this leaflet before you start taking this medicine

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets are and what they are used for
2. Before you take Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets
3. How to take Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets
4. Possible side effects
5. How to store Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets
6. Further information

1. WHAT CODEINE PHOSPHATE TABLETS 15 MG, 30 MG, AND 60 MG TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Codeine Phosphate 15mg, 30mg or 60mg Tablets. The active ingredient is codeine phosphate.

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 painkillers 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.

It can also be used to prevent coughs and to treat the symptoms of chronic diarrhoea.

2. BEFORE YOU TAKE CODEINE PHOSPHATE 15 MG, 30 MG AND 60 MG TABLETS

Do not take this medication:
- if you have ever had an allergic reaction to any of the ingredients of Codeine Phosphate 15 mg, 30 mg and 60 mg tablets or any other medicines that you may have taken to relieve pain. (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 have severe respiratory depression (e.g. asthma, breathing difficulties or problems)
- if due to heavy alcohol intake you have a risk of (paralytic ileus) paralysis or inactivity of the intestine that prohibits the passage of material within the intestine
- if you have a raised pressure in your head (intracranial pressure) or a head injury
- if you are pregnant, are planning to become pregnant, or are breast-feeding
- 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
- if you know that you metabolise codeine into morphine very rapidly

Take special care with this medicine and tell your doctor or pharmacist if:
- you have liver or kidney problems
- you have a history of asthma, liver or kidney problems, or drug abuse
- you have low blood pressure
• your doctor has told you that you have underactive thyroid glands (produces low quantities of thyroid hormone)
• you have Addison’s disease (inadequate secretion of corticosteroid hormones by the adrenal glands)
• you have an enlarged prostate gland (prostatic hypertrophy)
• you have severe abdominal problems e.g. ulcers or gas in the gut
• you have recently had surgery on your stomach
• you have gallstones
• you have a disease called ‘myasthenia gravis’ (it is marked by tiredness and weakness of some muscles e.g. eyes, mouth and throat muscles)
• you have a history of heart disease or failure; or convulsions

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.

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.

Tell your doctor before taking this medicine if you have been told that you have intolerance to some sugars. This is because codeine phosphate contains lactose, a type of sugar.

Tolerance and dependence (addiction) may occur in patients who are prescribed codeine phosphate for a long period of time. Your doctor will recommend a dose that is suitable for you.

Taking other medicines
Tell your doctor if you are taking any other medicines, especially the following:
• treatment for epilepsy e.g. phenobarbital sodium
• treatment for the thyroid e.g. potassium iodide tablets
• treatment for irregular heartbeat e.g. mexiletine
• alcohol e.g. drinks like beer or wine
• anaesthetics (used in surgical procedures) e.g. halothane
• treatment for insomnia or anxiety (hypnotics) e.g. diazepam or temazepam
• treatment for depression (tricyclic antidepressants) e.g. amitriptyline or dosulepin
• treatment for severe nausea and vomiting or schizophrenia (phenothiazides) e.g. promazine or pericyazine
• other treatments for diarrhoea e.g. co-phenotrope or loperamide hydrochloride
• muscle relaxants e.g. suxamethonium or mivacurium
• treatment for high blood pressure e.g. hydralazine
• treatment for ulcers e.g. cimetidine
• treatment with monoamine oxidase inhibitors (MAOIs) e.g. phenelzine or isocarboxazid

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

Other special warnings:
• Codeine interferes with laboratory tests e.g. tests for plasma amylase, lipase or bilirubin (substances found in the blood). Tell your doctor if you are having any blood tests done whilst you are taking codeine phosphate.

• Whilst you are taking this medicine, your doctor may want to give you a check up from time to time.

• Tell your doctor that you are taking Codeine Phosphate Tablets if you are going to have an operation of any kind.

Pregnancy and breast-feeding
Tell your doctor if you become pregnant.
Do not take codeine while you are breast-feeding. Codeine and morphine pass into breast milk.

Driving and using machines
This medicine can make you drowsy or cause blurred vision. Do not drive or operate machinery if you are affected. Do not drink alcohol whilst taking your tablets, this can affect your ability to drive.

3. HOW TO TAKE CODEINE PHOSPHATE 15 MG, 30 MG AND 60 MG TABLETS
Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual doses of Codeine Phosphate Tablets are as follows:

Adults
To relieve pain
30-60 mg every 6 hours or more, as required. If necessary, up to 240 mg daily.
To prevent coughing
15-30 mg 3 or 4 times daily.
To treat chronic diarrhoea
15-60 mg 3 or 4 times daily.
The dose maybe reduced for elderly patients.

Children
To relieve pain
Children aged 12 years or above should take 30-60 mg every 6 hours, as needed. Do not take more than 240 mg in 24 hours.
To prevent coughing or to treat chronic diarrhoea
Not suitable for children.

Codeine Phosphate Tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

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.

Do not stop taking your medicines suddenly. Ask your doctor how to reduce the dose gradually.

If you take more tablets than you should
If you accidentally take too much of your medicine, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

If you forget to take your medicine
If you forget to take a dose, just take the next dose at the usual time. DO NOT take a double dose.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Codeine Phosphate 15 mg, 30 mg and 60 mg Tablets can cause side effects, although not everybody gets them.

You are unlikely to get any of the following, but if you do, **tell your doctor immediately:**

- nausea or vomiting especially when you first start taking your tablets
- constipation
- tolerance (the body being able to take higher doses of the drug without adverse effects)
- sedation (reduction of anxiety, stress or excitement)
- dizziness and drowsiness
- difficulty passing urine
- abdominal spasms (sudden contraction of muscles)
- dry mouth, sweating, headache and facial flushing
- vertigo (a feeling of dizziness or being lightheaded)
- bradycardia (slowed heart rate) or tachycardia (rapid heart rate)
- palpitations (trembling, shaking, irregular heart beats)
- postural hypotension (low blood pressure on standing up from a sitting or lying position)
- hypothermia (abnormally low body temperature)
- hallucinations
- dysphoria (anxiety, depression, unease), mood changes
- dependence (addiction)
- miosis (narrowing of the pupil in the eye)
- decreased or increased sexual desire
- hypersensitivity reactions like nettle rash (hives) or severe itching have been reported
- inflammation of the pancreas occurring shortly after taking drugs containing codeine have been reported

If you notice any side effects mentioned above, please **tell your doctor or pharmacist.**

**Other side effects may include:**

- bronchospasm (difficulty in breathing)
- angioedema (swelling of the face)
- respiratory depression
- low blood pressure
- muscle rigidity (stiffness)

These effects are often mild and may wear off after a few days’ treatment. If they are severe or last for more than a few days, tell your doctor. Older people may be at more risk of these effects, particularly at the start of treatment.

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

**5. HOW TO STORE CODEINE PHOSPHATE 15 MG, 30 MG AND 60 MG TABLETS**

Do not use after the expiry date that is stated on the carton and bottle labels.

Do not store above 25°C. Do not put in the fridge.

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

Return any unused medicine to your pharmacist.

**6. FURTHER INFORMATION**

What Codeine Phosphate Tablets contain:
Each tablet contains the active substance, Codeine Phosphate.
The other ingredients are: lactose; maize starch; sodium starch glycollate and magnesium stearate.

What Codeine Phosphate Tablets look like and the contents of the pack:
Codeine Phosphate Tablets are white round tablets with no markings. They are available in packs of 50, 100 or 500 tablets.

**Marketing Authorisation Holder and Manufacturer**
Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR.

This leaflet does not contain all the available information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

The information in this leaflet applies only to Codeine Phosphate Tablets.

Date of preparation of leaflet: September 2013