What is in this leaflet

1 What Codeine Phosphate Tablets are and what they are used for

The product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. The tablets can be used on their own or in combination with other painkillers such as paracetamol. Codeine Phosphate Tablets are used for the relief of:

• mild to moderate pain.
• symptoms of a dry cough or diarrhoea.

2 What you need to know before you take Codeine Phosphate Tablets

Do not take Codeine Phosphate Tablets:

• if you are allergic (hypersensitive) to codeine or other opioids, or any of the ingredients in the table listed in section 6
• if you have difficulty breathing, or other chronic lung disease
• if you have suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision, headache or change of type of vision)
• if you are having an asthma attack
• if you have liver failure
• if you are on a medicine that affects the blood
• if you suffer with alcoholism
• if you are under 12 years old
• for patients 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 very rapidly into morphine
• if you are breast feeding.

Warnings and precautions

Tell your doctor or pharmacist before taking Codeine Phosphate Tablets if you:

• have liver or kidney problems
• have decreased adrenal glands (Addison’s disease) or high blood pressure caused by a tumour near the kidney (pheochromocytoma)
• have inflammatory bowel disease including severe bloody diarrhoea (pseudomembranous colitis)
• have gall bladder disease or gall stones
• have recently had surgery on your gastro-intestinal tract or urinary system
• have an enlarged prostate gland and have difficulty urinating, and are male
• have epilepsy

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Possible side effects

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

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:

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.

Codeine Phosphate Tablets with alcohol, drink and alcohol

Do not drink alcohol while taking Codeine Phosphate Tablets.

Swallow the tablets with water.
Pregnancy and breast-feeding

Do not use Codeine Phosphate Tablets during pregnancy unless advised by your doctor. Regular use during pregnancy may cause withdrawal symptoms in newborn babies. If you are pregnant or breast-feeding, talk to your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Codeine Phosphate Tablets may make you feel drowsy, confused or dizzy. Causes of a double vision or to see things that are not there. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if the medicine affects your ability to drive.
- Your blood pressure, heart rate, muscle stiffness, decrease in sex drive, difficulty breathing, low body temperature.

- slow or fast heart rate, palpitations, low blood pressure, low blood pressure on

Do not drive while taking this medicine.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Codine Phosphate Tablets contain Lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

How to take Codine Phosphate Tablets

Always take this medicine as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not drink alcohol whilst taking Codeine Phosphate Tablets. Swallow the tablets with water.

Codine Phosphate Tablets are normally used only for short-term relief of symptoms, take this medicine for as long as your doctor tells you, it may be dangerous to stop without their advice.

Do not:

- take more than 240mg in 24 hours.
- use regularly.
- take more than 3 times a day.
- take 3 times a day.

Use in children and adolescents:

Children aged 12 years or above:

For pain relief:

- 30 - 60mg every four hours up to a maximum of 240mg a day.
- 15 - 60mg three to four times a day.

For diarrhoea:

- 6 - 12mg three to four times a day.

Elderly patients with liver or kidney damage:

Your doctor may give you a smaller dose. If you are elderly, it is particularly important to take this medicine exactly as directed by the doctor.

Urinary system:

- pain and difficulty in passing urine and a less frequent need to do so.

For cough:

Children aged under 12 years:

Codeine Phosphate Tablets are not recommended for use in children under 12 years. Codeine Phosphate Tablets are not recommended for use in children aged 12 years or above if they have breathing problems. Talk to your doctor before taking this medicine if it applies to you.

Use in children and adolescents:

Children aged under 12 years:

- Constipation, feeling or being sick, abdominal pain

What Codeine Phosphate Tablets contain

The active ingredient is codeine phosphate (47.5% of Codeine), 47.5 mg of Codeine in each tablet.

The other ingredients are:

- Maltodextrin, maize starch, magnesium stearate, hypromellose, lactose monohydrate, talc, titanium dioxide, yellow iron oxide, black iron oxide, dextrose.

How to store Codeine Phosphate Tablets

Keep out of the sight of children.

Store below 25°C in a dry place, protected from light.

Do not use Codeine Phosphate Tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Contents of the pack and other information

What Codeine Phosphate Tablets contain

- The active substance (the ingredient that makes the tablets work) is codeine phosphate hydrobromide. Each tablet contains 10, 30 or 60mg of the active ingredient.

How to report side effects

If you (or someone else) feel that you are being affected by this medicine, talk to your doctor or pharmacist. You can report side effects and any other information using the Uniform Adverse Reaction Reporting Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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