Warning and precautions
Talk to your doctor or pharmacist before taking Codeine Phosphate Tablets if you:
• have liver or kidney problems
• have disease of the glands (Addison’s disease) or high blood pressure
• have disease of the kidneys (phaeochromocytoma or pheochromocytoma)
• have inflammatory bowel disease including severe bloody diarrhoea (pseudo-membranous colitis)
• have gall bladder disease or gall stones
• have recently had surgery on your gastrointestinal tract or urinary system
• have an enlarged prostate gland and have difficulty urinating and are male
• have epilepsy
• are elderly or frail
• suffer with asthma or breathing problems
• have an undescended testicle (testis) or have a history of testicular symptoms (gynecomastia)
• have low blood pressure or have a heart attack
• have suffered from alcoholism, drug abuse or dependence.

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 the 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: nausea, vomiting, difficulty 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:
• Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.
• Adolescents over 12 years of age:
• Codeine is not recommended in adolescents with compromised respiratory function for the treatment of cough.

Other important warnings
• Do not take for longer than directed by your prescriber.
• Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
• Taking a painkiller for headaches too often or for too long can make them worse.

Other medicines and Codeine Phosphate Tablets
Tell your doctor or pharmacist if you are taking, have recently taken any other medicines, including medicines obtained without a prescription or might take any other medicines. Especially:
• medicines to treat depression such as Monoamine Oxidase Inhibitors (MAOIs eg moclobemide, bupropion, venlafaxine; Avoid Codeine Phosphate Tablets for 2 weeks after stopping the MAOI or tricyclics eg amitryptiline)
• ophthalmics (antibacterial medicines)
• metoclopramide or domperidone (to prevent sickness)
• meperidine or quinidine (to treat irregular heartbeats)
• loperamide or kaolin (to treat diarrhoea)
• mexiletine or quinidine (to treat arrhythmias)
• moclobemide, linezolid, selegiline. Avoid Codeine Phosphate Tablets for 2 weeks before stopping the MAOI or tricyclics eg amitryptiline).
• medicines to treat depression such as Monoamine Oxidase Inhibitors (MAOIs eg moclobemide, bupropion, venlafaxine; Avoid Codeine Phosphate Tablets for 2 weeks after stopping the MAOI or tricyclics eg amitryptiline)
• ophthalmics (antibacterial medicines)
• metoclopramide or domperidone (to prevent sickness)
• meperidine or quinidine (to treat irregular heartbeats)
• loperamide or kaolin (to treat diarrhoea)
• mexiletine or quinidine (to treat arrhythmias)
Do not take codeine while you are breast-feeding. Codeine and morphine pass into breast milk. Usually it is safe to take Codeine Phosphate Tablets while breast-feeding 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, being sick, constipation, poor appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

Driving and using machines
Codeine Phosphate Tablets may make you feel drowsy, confused or dizzy, cause fits, blurred or 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 or fly. It is not usually necessary to stop driving or flying for the next 24 hours after taking a codeine phosphate tablet but check with your doctor before driving or flying if you need to travel while taking the medicine.

The medicine can affect your ability to drive a vehicle or operate machinery safely. It is not usually necessary to stop driving or using machinery for the next 24 hours after taking a codeine phosphate tablet but check with your doctor before driving or using machinery if you need to travel while taking the medicine.

The medicine can affect your ability to drive safely. It is not usually necessary to stop driving or using machinery for the next 24 hours after taking a codeine phosphate tablet but check with your doctor before driving or using machinery if you need to travel while taking the medicine.

If you are pregnant or breast feeding you must not take codeine phosphate tablets.

4. Possible side effects

Like all medicines, Codeine Phosphate Tablets can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed.

- Allergic Reactions - skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face.
- Gastrointestinal System - constipation, feeling or being sick, dry mouth, abdominal pain (may be caused by spasm of the bile ducts).
- Nervous System - dizziness, impaired coordination, depression, anorexia, dizziness, excessive sweating, increased heart rate, rash, dry mouth, abdominal pain (may be caused by spasm of the bile ducts).
- Urinary System - pain and difficulty in passing urine and a less frequent need to do so.
- Psychiatric effects - mood changes, depression, hallucinations (seeing or hearing things that are not there), restlessness, insomnia, nightmares, confusion.
- Eyes - blurred or double vision, extremely small pupil.
- Others - muscle stiffness, decrease in sex drive, difficulty breathing, low blood temperature.

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 out of the sight of and reach 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/coupon 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.

6. 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. Each tablet contains 15mg, 30mg or 60mg of the active ingredient.
- The other ingredients are lactose, magnesium stearate, pregelatinised maize starch, maize starch, stevias.

What Codeine Phosphate Tablets look like and contents of the pack
Codeine Phosphate Tablets are white, uncoated tablets.
Pack sizes are 28.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.
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