PACKAGE LEAFLET: INFORMATION FOR THE USER

Codeine phosphate 15 mg tablets
Codeine phosphate 30 mg tablets
Codeine phosphate 60 mg tablets
(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. This includes any possible side effects not listed in this leaflet. See section 4..

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 tablets belong to a group of medicines called opioid analgesics. Codeine phosphate tablets are used in:
- relief of mild to moderate pain
- symptomatic relief of coughing
- symptomatic relief of prolonged diarrhoea

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

Do not take Codeine phosphate tablets if:
- you know that you are allergic to Codeine phosphate, other opioid pain killers or any of the other ingredients (refer to **section 6** below)
- you have just had a head injury
- you suffer from any of the following:
  - liver disease
  - severe breathing problems
  - neck stiffness
  - acute alcoholism
  - diarrhoea associated with either severe inflammation of the bowel or poisoning

Warnings and precautions

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Codeine phosphate tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Codeine phosphate tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Codeine phosphate tablets, it could be a sign that you have become dependent or addicted:

– You need to take the medicine for longer than advised by your doctor
– You need to take more than the recommended dose
– You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain or cough.
– You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
– You have made repeated, unsuccessful attempts to quit or control the use of the medicine
– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Codeine phosphate tablets).

Sleep-related breathing disorders

Codeine phosphate tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor or pharmacist or nurse if you experience any of the following symptoms while taking Codeine phosphate tablets

• You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Take special care and tell your doctor or pharmacist before taking Codeine phosphate tablets if:

- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs, such as phenelzine or isocarboxazid, are medicines used to treat depression.
- you have a history of drug dependence, irregular heartbeat or convulsions.
- you have recently undergone gastro-intestinal surgery.
- you have been diagnosed as suffering from any of the following:
  - low blood pressure
  - deficiency in the activity of the thyroid gland
  - enlarged prostate
  - acute abdominal conditions
  - gallstones
  - severe weakness of muscles
  - asthma
  - reduced function of the adrenal glands, e.g. Addison's disease
- you have kidney problems, because the dose might need to be lower.

Other medicines and codeine phosphate tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Codeine is known to interfere with some medicines. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:
- MAOIs used to treat depression (refer to "Take special care" in **section 2** above)
- Phenobarbitone
- Potassium iodide
- Sedatives
- Hypnotics and alcohol
- other anti-diarrhoeal agents
- Neuromuscular blocking agents
- Anti-hypertensives
- Cimetidine
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Laboratory test results may also be affected.

Codeine phosphate tablets with food, drink and alcohol

Do not drink alcohol whilst taking Codeine phosphate tablets.
Alcohol may increase the sedative effects of Codeine phosphate tablets and make you very sleepy.
You can also take the tablets regardless of food intake.

Pregnancy, breast-feeding and fertility

Do not use this medicine if you are pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Usually, it is safe to take Codeine phosphate tablets while breast feeding as the level 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 for longer than normal, and shallow or slow breathing.

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

Driving and using machines

Do not drive or operate machinery because you may suffer from sedation (calming), dizziness. This can affect driving or the operation of machinery.

Important information about 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 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.

Codeine phosphate tablets contains lactose
This medicine contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Codeine phosphate tablets, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, if you stop taking Codeine phosphate tablets).

The recommended dose is:

For the relief of mild to moderate pain:
Adults: 30-60 mg every four hours, when necessary to a maximum of 240 mg daily.

For the relief and prevention of coughing:
Adults: 15-30 mg three or four times daily.

For the treatment of prolonged diarrhoea:
Adults: 10-60 mg every four to six hours.

Codeine phosphate tablets should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.

Codeine phosphate tablets are not recommended for children. A lower dosage may be needed if you are elderly. Swallow these tablets with water.

If you take more Codeine phosphate tablets than you should
If you take too many tablets contact your doctor or pharmacist at once for advice.

If you forget to take Codeine phosphate tablets
Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

If you stop taking Codeine phosphate tablets
Prolonged use can lead to tolerance and dependence on the medicine. Taking codeine regularly for a long time can be habit forming, which might cause you to feel restless and irritable when you stop the tablets. Your doctor will stop your tablets gradually to avoid you having withdrawal symptoms.
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 can cause side effects, although not everybody gets them.

If the following happens, stop taking Codeine phosphate tablets and tell your doctor immediately or contact the casualty department at your nearest hospital:
- Allergic reactions (itch, skin rash, facial oedema)
- Convulsions

Possible undesirable effects are:
- Sedation
- Dizziness
- Feeling sick (nausea)
- Constipation

Other possible frequent undesirable effects are:
- Sweating
- Facial flushing
- Dry mouth
- Blurred or double vision
- Low blood pressure
- Malaise (general discomfort)
- Headache
- Loss of appetite
- Slow heart beat
- Difficulty in passing water

Rare side effects are:
- Hallucinations
- Nightmares
- Uncontrolled muscle movements and rigidity
- Mental depression
- Stomach cramps

Not known side effects are:
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google play or Apple App Store. 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 use Codeine phosphate tablets after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

Store this medicine in a safe and secure storage space, where other people cannot access it.

It can cause serious harm and be fatal to people when it has not been intended for them.

Store below 25°C. Store the tablets in the original packaging. Do not put them in another container. For container packaging, replace the cap securely after use.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Codeine phosphate tablets contains:
- The active substance is codeine phosphate. Each tablet contains 15 mg, 30 mg or 60 mg of codeine phosphate.
- The other ingredients are lactose, starch, magnesium stearate and sodium starch glycolate.

What Codeine phosphate tablets looks like and contents of the pack
Codeine phosphate 15 mg tablets are white, circular normal biconvex tablets embossed with R114
Codeine phosphate 30 mg tablets are white, circular normal biconvex tablets embossed with R115
Codeine phosphate 60 mg tablets are white, circular normal biconvex tablets embossed with R117

The tablets are available in 15 mg, 30 mg and 60 mg strengths and in containers of 1000, 500, 100, 90, 80, 70, 60, 50, 40, 30, 20 and 10 tablets and in blister strips of 100, 90, 80, 70, 60, 50, 40, 30, 20 and 10 tablets. The 30 mg strength is also available in blister strips of 28 tablets.

Marketing Authorisation Holder:
Activase Pharmaceuticals Limited
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Manufacturer:
Ranbaxy Ireland Ltd.,
Spafield, Cork Road, Cashel,
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This leaflet was last revised in 02/2026