

FLAT DIMENSION = 180 x 560mm
FOLDED DIMENSION = 180 x 35mm

Package Leaflet: Information For The User

Codeine Phosphate Tablets BP 15 MG
Codeine Phosphate Tablets BP 30 MG
(codeine phosphate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine contains codeine phosphate which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- Keep this leaflet. You may need 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:

- What Codeine Phosphate is and what it is used for
- What you need to know before you take Codeine Phosphate
- How to take Codeine Phosphate
- Possible side effects
- How to store codeine Phosphate
- Contents of the pack and other information

1. What Codeine Phosphate is and what it is used for

This medicine has been prescribed for you to relieve pain. This product contains codeine which belongs to a class of medicines called opioids, which are ‘pain relievers’. It can be used on its own or in combination with other pain killers such as paracetamol. This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Codeine Phosphate Tablets are used for the relief of:

- mild to moderate pain.

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 pain killers such as paracetamol or ibuprofen alone.

- symptoms of a dry cough or diarrhoea.

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

Do not take codeine phosphate:

- if you are allergic (hypersensitive) to codeine or other opioids, or any of the

- ingredients in the tablet (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 or headache behind the eyes)
- if you are having an asthma attack
- if you have liver failure
- if you are at risk of blocked intestines
- if you suffer with alcoholism
- if you are under 12 years old
- 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 very rapidly into morphine
- if you are breast-feeding
- if you have diarrhoea associated with either severe inflammation of the bowel or poisoning

Warnings and Precautions

Talk to your doctor or pharmacist before taking Codeine tablets if you:

- have kidney or liver problems
- are elderly or frail
- have low blood pressure or an under-active thyroid gland or are in shock
- have diseased adrenal glands (Addison’s disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
- have an enlarged prostate gland and have difficulty urinating and are male.
- have inflammatory bowel disease including severe bloody diarrhoea (pseudomembranous colitis)
- have gall bladder disease or gall stones
- recently had surgery on your gastro-intestinal tract or urinary system
- suffer from muscle weakness (myasthenia gravis) or asthma or breathing problems
- have a history of seizures or fits (epilepsy)
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of this medicine to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- 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.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking codeine:

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

Sleep-related breathing disorders

Codeine 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.

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.

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.

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 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 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 , 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).

Children and adolescents

Use in children and adolescents after surgery

Codeine Phosphate 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 Phosphate is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Adolescents older than 12 years of age

Codeine Phosphate 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

Please tell your doctor or pharmacist if you are taking or 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 e.g. moclobemide, linezolid, selegiline. Avoid Codeine Phosphate tablets for 2

weeks after stopping the MAOI) or tricyclics (e.g. amitriptyline)

- ciprofloxacin (antibacterial medicine)
- metoclopramide or domperidone (to prevent sickness)
- mexiletine or quinidine (to treat irregular heartbeats)
- loperamide or kaolin (to treat diarrhoea)
- cimetidine (to treat stomach ulcers)
- medicines to treat high blood pressure, anti-hypertensives
- phenobarbitone (medicine used for control of fits)
- hypnotics and alcohol
- cimetidine (to treat stomach ulcers)
- tricyclics antidepressants (eg amitriptyline)
- antiviral medicines such as ritonavir
- medicines to treat allergies (antihistamines) that can cause drowsiness
- atropine (anticholinergic medicines)
- medicines which affect the nervous system (chlorpromazine, diazepam, temazepam)
- anaesthetics
- opioid antagonists (buprenorphine, naltrexone, naloxone)
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

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 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 take the tablets regardless of food intake.

Pregnancy, breast-feeding and fertility

Do not take codeine phosphate if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

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