

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:

- 1. What Codeine Phosphate is and what it is used for**
- 2. What you need to know before you take Codeine Phosphate**
- 3. How to take Codeine Phosphate**
- 4. Possible side effects**
- 5. How to store codeine Phosphate**
- 6. 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

Check with your doctor or pharmacist before taking this medicine 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.

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.

Taking this medicine regularly, particularly for a long time, can lead to addiction. 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. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Children and adolescentsUse 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)
- tricyclic 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)

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.

If you use codeine phosphate during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Codeine Phosphate Tablets while you are breast-feeding as codeine passes into breast milk and will affect your baby. Some women who are at increased risk of developing side effects at any dose may have higher levels of codeine 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, being sick, constipation, poor appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

xxxxxx

FLAT DIMENSION = 180 x 560mm

FOLDED DIMENSION = 180 x 35mm

Driving and using machines

Do not drive or operate machinery because you may suffer from confusion, drowsiness, hallucinations (seeing, feeling or hearing things that are not there), blurred or double vision, fits or dizziness. This can affect driving or the operation of machinery.

Codeine Phosphate 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 this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

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

If you feel that your reactions are affected, do not operate machinery.

Codeine Phosphate tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicine.

3. How to take Codeine Phosphate

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow the tablets with water.
- Codeine Phosphate Tablets are normally used only for short-term relief of symptoms, take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

The usual dose is as follows:

Adults:

For pain relief – 30 - 60mg every four hours up to a maximum of 240mg a day.

For diarrhoea – 15 - 60mg three to four times a day.

For cough – 15 - 30mg 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.

Use in children and adolescents:

Children aged 12 years or above:

For pain relief - 30 - 60mg every 6 hours, as needed. **Do not** take more than 240mg in 24 hours.

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.

Codeine Phosphate Tablets should not be used for pain relief in children aged 12 years or above after removal of tonsils or adenoids (see **Warnings and Precautions**).

Talk to your doctor before taking this medicine if this applies to you.

For diarrhoea –15 - 60mg three to four times a day.

For cough - 15 - 30mg three to four times a day.

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

Children under 12 years:

Codeine Phosphate Tablets **are not** recommended for use in children under 12 years. Codeine Phosphate Tablets **must not** be taken by children below the age of 12 years for treatment of cough, due to risk of severe breathing problems.

If you take more Codeine Phosphate tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, confusion, fits, dizziness, nervousness, restlessness, excitement, hallucinations, muscle weakness, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate.

If you forget to take a dose of Codeine Phosphate tablets

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

If you stop taking these tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you stop taking the tablets you may develop the following withdrawal symptoms tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure, restlessness, irritability, anxiety, depression, anorexia, diarrhoea, excessive tears, runny nose, sneezing, yawning, hair standing on ends, widening of the pupil, weakness, fever, muscle cramps, dehydration.

4. Possible side effects

Like all medicines, this medicine 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, hives
- Gastrointestinal system - constipation, feeling or being sick, dry mouth, abdominal pain (may be caused by spasm of the bile ducts)
- increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes)
- fits (convulsions)

Other side effects

- confusion, dizziness, drowsiness, tiredness, changes in mood, nightmares, mental depression
- restlessness/excitement
- headache
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling sick (nausea), constipation, vomiting, dry mouth
- abdominal pain (may be caused by spasm of the bile ducts)
- low body temperature
- blurred or double vision, extremely small pupils
- palpitations, low blood pressure, low blood pressure on standing, slow or fast heart beat
- malaise (general discomfort)
- pain and difficulty in passing water and a less frequent need to do so
- uncontrolled muscle movements and rigidity
- decrease in sex drive.

Tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)

Not known frequency: dependence and addiction (see section “How do I know if I am addicted?”).

Drug Withdrawal

When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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

Website: 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

- Keep this medicine out of the sight and reach of children.
- Containers: Do not store above 25°C. Store in the original container and keep the container tightly closed.
- Blister packs: Do not store above 25°C. Store in the original package.
- Do not use these tablets after the expiry date which is stated on the carton or label. 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 protect the environment.

6. Contents of the pack and other information

What Codeine Phosphate tablets contain

- The active substance is codeine phosphate.
- The other ingredients are: lactose and stearic acid.
- Codeine Phosphate tablets come in two strengths. Each tablet contains either 15mg or 30mg of the active ingredient codeine phosphate.

What Codeine Phosphate tablets look like and contents of the pack

- The tablets are smooth, round, flat faced, bevelled edge plain white to off white
- They are available in packs of 14, 25, 28, 30, 50, 56, 60, 84, 100, 250, 500 or 1000.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire,
HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922

Fax: 0044 (0)1442 873717

E-mail: info@bristol-labs.co.uk

Codeine Phosphate Tablets BP 15 mg; PL 17907/0168

Codeine Phosphate Tablets BP 30 mg ; PL 17907/0169

This leaflet was last revised in May 2023

To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

V4 26-05-23 D0

XXXXXX