CODEINE PHOSPHATE 15 mg AND 30 mg TABLETS

Package leaflet: Information for the user
This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly. 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 the symptoms are the same as yours. If you receive any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What Codeine Phosphate is and what it is used for
This medicine has been prescribed for you to: treat mild to moderate pain suppress a troublesome cough treat diarrhoea. It contains codeine phosphate which belongs to a class of medicines called opioids, which are ‘pain relievers’. 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, and how to do this safely. Your tablets are called Codeine Phosphate Tablets. Codeine Phosphate Tablets contain the active substance codeine. Codeine Phosphate Tablets 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. If you are travelling abroad, you may require a letter from your doctor explaining why you need to take these tablets.

What you need to know before you take Codeine Phosphate
Do not take Codeine Phosphate:
if you are allergic to Codeine Phosphate or any of the other ingredients of this medicine (listed in section 6)
if you suffer from liver disease
if you suffer from alcoholism
if you suffer from breathing difficulties or are having an asthma attack, since the symptoms of morphine toxicity may be worse in such patients
if you suffer from colitis (inflammation of the colon) or risk of a blockage in your gut
if you have recently had a head injury, or you suffer from raised pressure in your head (this may cause vomiting, headache and changes in behaviour)
if you metabolise very slowly codeine into morphine
if you are breast-feeding
if you are under 12 years old
for pain relief in children and adolescents (0-12 years old) after removal of their tonsils or adenoids due to obstructive sleep apnoea

Warnings and precautions
Talk to your prescriber before taking this medicine if:
are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
if you feel you need to take more of Codeine phosphate to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or 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.

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 it more difficult to control 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 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.

DO NOT take Codeine Phosphate for longer than directed by your prescriber.

Taking Codeine Phosphate as a painkiller for headaches too often or for too long can make them worse.

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

Talk to your doctor before you start to take this medicine:
if you have suffered from alcoholism, drug abuse or dependence
if you have diarrhoea which is known to be caused by an infection
if you have low blood pressure
if you have prostate problems
if you have problems with your thyroid gland
if you have problems with your kidneys
if you have liver impairment
if you suffer from asthma
if you suffer from chronic bronchitis
if you suffer from fits.

Children and adolescents
Codeine Phosphate should not be used in children below the age of 12 years because of the risk of opioid toxicity due to the variance and unpredictable metabolism of codeine to morphine. Adolescents older than 12 years of age

Adolescents is not recommended for use in adolescents aged 12 years to 18 years with compromised respiratory function for the treatment of cough.

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.

Other medicines and Codeine Phosphate:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Codeine Phosphate:
if you are taking or have recently stopped taking (within the last 2 weeks) monoamine oxidase inhibitors (MAOIs) for the treatment of depression.

Talk to your doctor if you are taking any of the following:
tranquilizers, diazepam, lorazepam, alprazolam or one of the benzodiazepine medications used to treat mental disorders e.g. chlorpromazine
aprazolam or oxazepam
ritonavir or cimetidine
antidepressants.

Comitant use of Codeine Phosphate and sedative medicines such as benzodiazepines or related drugs increases the risk of drug interactions, 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 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 and drink
DO NOT drink alcohol with Codeine Phosphate, as it may affect you more than usual.

Pregnancy and breast-feeding
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 while you are breastfeeding as Codeine Phosphate passes into breast milk and will affect your baby.

Driving and using machines
The medicine can affect your ability to drive as it may make you sleepy or drowsy.

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

The medicine has been prescribed to treat a medical or dental problem

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.
Codine Phosphate contains lactose
• Patients who are intolerant to lactose should note that Codine Phosphate tablets contain a
small amount of lactose. If your doctor has told you that you have an intolerance to some sugars,
contact your doctor before taking this medicine.

3 How to take Codine Phosphate
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor if you are not sure.
Your prescriber should have discussed with you, how the dose or number 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.
Do not take a higher dose or more often than the doctor has told you.
The recommended dose is:

Adults
Pain relief
30 – 60 mg every four hours when necessary, up
to a maximum of 240 mg in 24 hours.
Treatment of diarrhoea
30 mg three to four times daily.
Treatment of cough
10 - 30 mg three to four times daily.
Use in children and adolescents
Children aged 12 years to 18 years
The recommended codeine dose for children
12 years and older should be up to a maximum
dose of codeine of 240 mg daily.
Analgesic use
30 - 60 mg every 6 hours as needed. The dose is
based on the body weight (0.5 - 1 mg/kg).
For cough
The dose is based on bodyweight 1 - 2 mg/kg daily
in 4 to 6 divided doses.
The use of cough suppressants containing codeine is
not generally recommended in children.
Anti-diarrhoeal use
Not recommended.
Children aged under 12 years:
Codine phosphate is not suitable for use in
children under 12 years of age, due to the risk of
severe respiratory problems.
The Elderly, or patients with liver or kidney problems:
• A reduced adult dosage, as prescribed by your
doctor.
The tablets should be swallowed preferably with
a drink of water.
The medicine should not be taken for more than
3 days and if no effective pain relief is achieved
the patient/ carers should be advised to seek the
views of your doctor.
If you take more Codine Phosphate than you
should
If you (or someone else) swallow a lot of the tablets
together, or if you think a child has swallowed
any of the tablets, contact your nearest hospital
casualty department or your doctor immediately.
An overdose is likely to cause breathing problems,
nausea (feeling sick) and vomiting. An overdose
can lead to death. Please take this leaflet, any
remaining tablets, and the container with you
to the hospital or doctor so that they know which
tablets were consumed.
If you forget to take Codine Phosphate
If you forget to take a tablet, take one as soon as
you remember, unless it is nearly time to take the
next one. Do not take a double dose to make up for
a forgotten dose.
If you stop taking Codine Phosphate
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 withdrawal effects are kept to a minimum.
Withdrawal symptoms such as restlessness, difficulty sleeping, irritability,
agitation, anxiety, feeling your heartbeats,[palpitations], increased blood pressure, feeling or
being sick, diarrhoea, shaking, shivering or sweating
may occur. If you suddenly stop taking this medicine.
If you have any further questions on the use of this
medicine, ask your doctor or pharmacist.

4 Possible side effects
Like all medicines, Codine Phosphate can cause side effects, although not everybody gets them.
Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.
The following side effects have been reported:
• Allergic reactions: rash, itching, hives, chills, redness,
breathing difficulties, increased sweating
• Gastrointestinal system: constipation, abdominal pain (may be caused by strain of the bile ducts),
nausea (feeling sick), vomiting (being sick), dry mouth, pancreatitis (inflammation of pancreas,
which causes severe pain in the abdomen and back)
• Heart: change in heart rate (either faster or slower), palpitations, low blood pressure
• Urinary system: pain and difficulty in passing urine and a less frequent need to do so
• Nervous system: drowsiness, a general feeling of restlessness, uneasiness or of being unwell
(usually), tiredness, dizziness, a sensation that your surroundings are spinning either up and
down or from side to side, fits, increased pressure in the skull (painful eyes, changes in
vision or headache behind the eyes), incoordination, tolerance (medicine has less effect) or
dependence (sufferers from withdrawal symptoms e.g. tremor, sweating, increased heart rate,
increased breathing rate, raised blood pressure or feeling or being sick if the medicine is
stopped too quickly)
• Psychiatric effects: mood changes, depression,
hallucinations (feeling or seeing things that are not real), restlessness, excitement, nightmares,
confusion, dependence and addiction (see section “How do I know if I am addicted?”)
• Eyes: blurred or double vision, pinpoint pupils
• Others: muscle stiffness, low body temperature, reduced sex drive, impotence, difficulty
breathing, impaction of the faeces may occur, particularly in elderly patients, which could lead
to incontinence, unexplained diarrhoea, abdominal pain and in rare cases, obstruction of
the intestine.
Drug Withdrawal
When you stop taking Codine Phosphate, you may experience drug withdrawal symptoms, which include
restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeats
(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 Codine Phosphate, 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 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 Codine Phosphate
Keep this medicine out of the sight and reach of
children.
Do not store above 25°C. Protect from light.
Do not use Codine Phosphate after the expiry date
that is stated on the outer packaging. 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 Codine Phosphate tablets contain
• The active ingredient is codeine phosphate,
either 15 mg or 30 mg.
• The other ingredients are dextrose, lactose, and
magnesium stearate.
What Codine Phosphate tablets look like and
contents of the pack:
• Codine Phosphate tablets are white to-off-white,
biconvex tablets. The tablets are marked as
follows:
• 15 mg tablets: "APS" on one side and "15/0507" on
the reverse,
or APS" over "0507" on one side and plain on the
reverse.
• 30 mg tablets: "APS" on one side and "30/0508" on
the reverse,
or "APS" over "0509" on one side and plain on the
reverse.
• The tablets are available in pack sizes of 7, 10, 14,
21, 28, 30, 56, 60, 84, 90, 100, 110, 120, 125, 150,
160, 189, 200 and 1000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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