

Package leaflet: Information for the user

Co-codamol 15/500mg Film-coated Tablets

Codeine phosphate hemihydrate/paracetamol

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 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.

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1 What Co-codamol is and what it is used for

The name of your medicine is Co-codamol. Co-codamol can be used in adults and children over 12 years of age for the short-term relief of moderate or severe pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

This medicine contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed for 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 doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. This medicine also contains paracetamol, another analgesic to relieve pain.

2 What you need to know before you take Co-codamol

Do not take Co-codamol if you:

- are allergic to codeine, paracetamol or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- have severe asthma attacks or severe breathing problems
- have recently had a head injury
- have severe liver problems
- have been told by your doctor that you have

increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred eyesight

- have recently had an operation on your liver, gallbladder or bile duct (biliary tract)
- are taking medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypamine (see 'Other medicines and Co-codamol')
- have acute alcoholism
- are breast-feeding
- know that you metabolise codeine very rapidly into morphine.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

Do not use this product 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-codamol if:

- you have severe kidney problems
- you have liver problems or are an alcoholic
- you have problems passing water or prostate problems
- you have an underactive thyroid gland
- you have problems with your adrenal glands
- you have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel
- you are elderly
- you are sensitive to aspirin or other medicines used for the treatment of inflammation (Non-Steroidal Antiinflammatory Drugs) such as ibuprofen.
- you have anaemia (a reduced number of red blood cells)
- you are malnourished or dehydrated
- the person going to take the tablets is under 18 years of age and has breathing problems.

Talk to your doctor before taking this medicine if you:

- 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 Co-codamol 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 doctor 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 doctor 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 doctor 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 doctor 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.

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

Never take more Co-codamol than recommended. Talk to a doctor at once if you take too much of this medicine, even if you seem well. This is because too much paracetamol can cause delayed, serious liver damage.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. 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. 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.

Children and adolescents

Co-codamol should not be taken by children under 12 years of age.

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 and adolescents with breathing problems

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

Other medicines and Co-codamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important in the case of:

- Medicines to treat depression.
- Medicines which make you drowsy or sleepy (Central Nervous System depressants) such as sleeping pills, medicines to treat anxiety or anaesthetics.
- Medicines used to thin the blood such as warfarin.
- Medicines for irregular heartbeats such as quinidine.
- Antibiotics used to treat infections (e.g. chloramphenicol, rifampicin).
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Cholestyramine - for lowering blood cholesterol levels.
- Probenecid - used to treat gout.
- The herbal remedy 'St. John's Wort'.
- Cimetidine - used to treat heartburn and peptic ulcers.
- Other painkillers.
- Barbiturates (e.g. phenobarbital).
- Medicines to treat epilepsy (e.g. phenytoin, carbamazepine).
- The oral contraceptive pill.

Concomitant use of Co-codamol 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 Co-codamol 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.

While taking Co-codamol you should not take any other medicines which contain paracetamol.

This includes some painkillers and cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Co-codamol with food, drink and alcohol

You should not drink alcohol while you are taking these tablets. This is because alcohol can increase the risk of serious side effects.

Pregnancy and breast-feeding

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

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

Do not take Co-codamol while you are breastfeeding as codeine passes into breast milk and will affect your baby.

Driving and using machines

You may feel dizzy or sleepy while taking Co-codamol. If this happens, do not drive or use any tools or machines.

The medicine 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 doctor 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.

How to take Co-codamol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. 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.

- **Do not take more than the recommended dose**
- **Do not take for longer than your doctor or pharmacist tells you to**
- **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**

Take this medicine by mouth.

Swallow the tablets whole with a drink of water. If necessary, the tablets may be broken in half to make them easier to swallow.

Adults

The recommended dose of Co-codamol is 1 or 2 tablets. Wait at least 4 to 6 hours before taking another dose. Do not take more than 8 tablets in any 24-hour period.

Elderly people may be prescribed a lower dose.

Patients with kidney problems may require longer intervals between doses.

Children under 12 years

Co-codamol should not be given to children under 12 years of age, due to the risk of severe breathing problems.

Children and adolescents 12 to 15 years

The recommended dose of Co-codamol is 1 tablet. Wait at least 6 hours before taking another dose. Do not take more than 4 tablets in any 24-hour period.

Adolescents aged 16 years and above and over 50kg of body weight

The recommended dose of Co-codamol is 1 or 2 tablets. Wait at least 6 hours before taking another dose. Do not take more than 8 tablets in any 24-hour period.

If you take more Co-codamol than you should

- Tell your doctor or go to your nearest hospital casualty department straight away - even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you forget to take Co-codamol

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

However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 to 6 hours between doses for adults and 6 hours between doses for children and adolescents.

If you stop taking Co-codamol

Changing or stopping treatment

Long term usage of Co-codamol may lead to tolerance and dependence. Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects you should know about

- Taking a painkiller for headaches too often or for too long can make them worse.
- 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.

Stop taking Co-codamol and see a doctor or go to a hospital straight away if:

- You have difficulty in breathing or you feel dizzy.
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to Co-codamol.
- You get serious skin reactions. Very rare cases have been reported (Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis).

Talk to your doctor straight away if you notice the following serious side effect:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.

Other side effects:

Common: may affect up to 1 in 10 people: Drowsiness, headache, abnormal sweating, feeling sick (nausea), being sick (vomiting), constipation, tiredness.

Uncommon: may affect up to 1 in 100 people: Dizziness, problems with vision, dryness of the mouth.

Rare: may affect up to 1 in 1,000 people: You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia, pancytopenia, anaemia or thrombocytopenia). Difficulty sleeping, breathlessness, yellowing of the skin or white of the eyes (symptoms of liver damage), skin rash.

Very Rare: may affect up to 1 in 10,000 people: Kidney damage has been shown to occur very rarely in patients receiving long term treatment with Co-codamol.

Unknown: frequency can not be estimated from the data:

Difficulty breathing, wheezing, tightness in the chest (bronchospasm), dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Co-codamol, 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 Co-codamol, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your doctor
- 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 doctor.

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 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 Co-codamol

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton or label after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Co-codamol contains

The active substances are codeine phosphate hemihydrate and paracetamol. Each film-coated tablet contains 15mg of codeine phosphate hemihydrate and 500mg of paracetamol.

The other ingredients are povidone (K29/32), magnesium stearate, colloidal silica anhydrous, talc, croscarmellose sodium, copovidone (25.2-30.8), microcrystalline cellulose, hypromellose, macrogol 3350, titanium dioxide (E171) and iron oxide yellow (E172).

What Co-codamol looks like and contents of pack

Co-codamol 15/500mg film-coated tablets are light yellow, oval, 8.5 x 17mm, biconvex tablets, marked '5 15' on one side with a score line.

Pack Sizes: White PVC/Aluminium/paper child resistant blisters: 100 film-coated tablets.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.