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Front Panel

130 mm

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PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Co-codamol 15mg/500mg and 30mg/500mg tablets

Codeine Phosphate
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 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 Co-codamol is and what it is used for
2. What you need to know before you take Co-codamol
3. How to take Co-codamol
4. Possible side effects
5. How to store Co-codamol
6. Contents of the pack and other information

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

The name of your medicine is Co-codamol tablets (called Co-codamol throughout this leaflet). Co-codamol contains two different medicines called codeine phosphate and paracetamol. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperature). Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other painkillers such as paracetamol. Co-codamol are used to treat pain. Co-codamol can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

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

Important things you should know about Co-codamol
- Do not take for longer than your doctor tells you to
- This medicine contains paracetamol. If you do not get better, talk to your doctor.
- Do not take anything else containing paracetamol while taking this medicine.
- Do not use Co-codamol for pain relief in children and adolescents (0-18 years of age) after the removal of their tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping this medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Rarely increasing the dose of this medicine can make you sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
- 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 does 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

Warnings and precautions

Do not take Co-codamol and tell your doctor if:
- You are allergic to the active substances or any of the other ingredients in your 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.
- You have severe asthma attacks or severe breathing problems.
- you suffer from severe kidney or liver disease
- You have recently had a head injury.
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred vision.
- You have recently had an operation on your liver, gallbladder or bile duct.
- You are taking medicine 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 tranylcypramine (see 'Other medicines and Co-codamol').
- You are an alcoholic
- The person going to take the tablets is under 12 years of age. Co-codamol must not be given to children under 12 years of age.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
- You know you metabolise very rapidly codeine into morphine
- You are breastfeeding or planning to breastfeed
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Do not take Co-codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-codamol

Take special care and check with your doctor before taking Co-codamol if:
- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Have previously suffered withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- Feel you need to take more 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 you prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- You have severe kidney, liver or thyroid problems because the dose might need to be lower
- you are prone to suffer from asthma
- You have problems passing water or prostate problems.
- 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 anti-inflammatory drugs such as Ibuprofen.
- You are taking a benzodiazepine.
- If you know you are slow or intermediate metabolizer of enzyme called CYP2D6, because a different dose may be applicable to you.
- If you are taking medicine that induces CYP3A4 enzyme activity such as rifampicin.
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you have problems with your adrenal glands (Addison's disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)

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 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. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Sleep-related breathing disorders
Co-codamol 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.

Children and adolescents

Use in children and adolescents after surgery
Co-codamol should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome. They may be at increased risk of severe side effects in case of morphine toxicity

Use in children with breathing problems
Co-codamol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children. If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Co-codamol
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Co-codamol can affect the way some other medicines work. Also, some other medicines can affect the way Co-codamol works. 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, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine, and tell your doctor, if you 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, tranylcypramine

Tell your doctor or pharmacist if you are taking any of the following medicines, or have taken them in the past two weeks:
- Medicines which make you drowsy or sleepy (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.
- Anti-depressant medicines such as imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine.
- Anti-histamine medicines used to treat allergies

Tell your doctor or pharmacist if you are taking any other medicines.
- Medicines used to thin the blood such as warfarin.
- Chloramphenicol - an antibiotic used for infections.
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine - for lowering blood cholesterol levels.
- The oral contraceptive pill.
- Medicines such as quinidine, fluoxetine, paroxetine, bupropion, cinacalcet, methadone or rifampicin, as they may alter the effect of Co-codamol.
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- phenothiazines (medicines that calm your mood) or tricyclic antidepressants
- antihypertensive drugs, diuretics (water pills)
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- patients should not take any other paracetamol containing medicines whilst taking Co-codamol. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Co-codamol can interfere with some laboratory tests used for determining some diseases.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-codamol.

Talk to your doctor or pharmacist if you experience any of the following symptoms while using Co-codamol
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Taking Co-codamol food and drinks
You should not drink alcohol while you are taking these tablets.
This is because taking Co-codamol can change the way alcohol affects you.

Pregnancy and breast-feeding
Do not take Co-codamol and Talk to your doctor before taking these tablets:
- You are pregnant, think you may be pregnant or plan to get pregnant
- You are planning to breastfeed
- Do not take Co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.
- as they can affect the baby and can cause breathing problems when the baby is born.

Driving and using machines
Co-codamol can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive whilst 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 whilst taking this medicine

Changing or stopping treatment
Chronic usage of Co-codamol may lead to tolerance and dependence. If you have taken regular daily doses of Co-codamol for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

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 Co-codamol 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 Co-codamol 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 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 Co-codamol).

3. How to take Co-codamol

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

Your prescriber should have discussed with you, how long the course of Co-codamol will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.
Always take Co-codamol exactly as your doctor has told you. 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 Co-codamol, 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 Co-codamol).
- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to
- Swallow the tablets whole with a drink of water

Adults: 2 tablets every 4 to 6 hours up to a maximum of 8 tablets in 24 hours. Elderly people may be prescribed a lower dose.
If you feel the effect is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist. 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.
A lower dosage may be needed if you are elderly or have other medical problems.
Check with your doctor about this.
Do not take with any other paracetamol-containing products.

Use in children aged 16 to 18 years: 1-2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Use in children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of 4 tablets 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.

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

If you take more Co-codamol than you should
- Talk to a doctor at once if you take too much of this medicine 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 do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

If you stop taking Co-codamol
You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. If you suddenly stop taking these tablets you may get withdrawal symptoms such as, agitation, anxiety, palpitations, shaking or sweating.

Co-codamol should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Important side-effects you should know about Co-codamol
- 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 taking the tablets.

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

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

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:
- Constipation
- Feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)
- Frequency "Not known" (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Other possible side effects:
- Not known (frequency cannot be estimated from the available data):
  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.

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 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 Co-codamol

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.

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. Do not throw away 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

Co-codamol 15mg/500mg:
- The active substance is Paracetamol and Codeine Phosphate. Co-codamol 15mg/500mg tablets contain 500mg of Paracetamol and 15mg of Codeine Phosphate hemihydrate per tablet
- The other ingredients are Pregelatinized maize starch, Stearic acid, Povidone K-30, Lactose monohydrate, Powdered cellulose, Talc, Magnesium stearate.

Co-codamol 30mg/500mg:
- The active substance is Paracetamol and Codeine Phosphate. Co-codamol 30mg/500mg tablets contain 500mg of Paracetamol and 30mg of Codeine Phosphate hemihydrate per tablet
- The other ingredients are Pregelatinized maize starch, Stearic acid, Povidone K-30, Lactose monohydrate, Powdered cellulose, Talc, Magnesium stearate.

What Co-codamol looks like and contents of the pack
Co-codamol 15mg/500mg tablets are white to almost white, capsule-shaped, biconvex, bevelled edged tablets, with 'CCD' on one side and 'score line' on the other side.

Co-codamol 30mg/500mg tablets are White to almost white, capsule-shaped, flat, bevelled edged tablet. The tablet is debossed with 'CCI' on one side and 'score line' on the other side.

Co-codamol 15mg/500mg tablets are available in cartons containing 30, 50 and 100 tablets in blisters. They are also available in bottle containing 100 tablets. Each carton contains one bottle.

Co-codamol 30mg/500mg tablets are available in cartons containing 30, 50 and 100 tablets in blisters. They are also available in bottle containing 100 and 250 tablets. Each carton contains one bottle.

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Back Panel

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Size: 130x580 mm

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Size: 130x580 mm

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Department	**Contract Giver/ PL holder**	**Regulatory Affairs**	**Packaging Development**	**Head Production/ Packing (Site)**	**Head QA (Site)**
Sign / Date					

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PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Co-codamol 15mg/500mg and 30mg/500mg tablets

Codeine Phosphate
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 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 Co-codamol is and what it is used for
2. What you need to know before you take Co-codamol
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1. What Co-codamol is and what it is used for

The name of your medicine is Co-codamol tablets (called Co-codamol throughout this leaflet). Co-codamol contains two different medicines called codeine phosphate and paracetamol. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperature). Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other painkillers such as paracetamol. Co-codamol are used to treat pain. Co-codamol can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

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

Important things you should know about Co-codamol
- Do not take for longer than your doctor tells you to
- This medicine contains paracetamol. If you do not get better, talk to your doctor.
- Do not take anything else containing paracetamol while taking this medicine.
- Do not use Co-codamol for pain relief in children and adolescents (0-18 years of age) after the removal of their tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping this medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Rarely increasing the dose of this medicine can make you sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
- 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 does 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

Warnings and precautions

Do not take Co-codamol and tell your doctor if:
- You are allergic to the active substances or any of the other ingredients in your 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.
- You have severe asthma attacks or severe breathing problems.
- you suffer from severe kidney or liver disease
- You have recently had a head injury.
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred vision.
- You have recently had an operation on your liver, gallbladder or bile duct.
- You are taking medicine 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 tranylcypramine (see 'Other medicines and Co-codamol').
- You are an alcoholic
- The person going to take the tablets is under 12 years of age. Co-codamol must not be given to children under 12 years of age.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
- You know you metabolise very rapidly codeine into morphine
- You are breastfeeding or planning to breastfeed
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking fluclоxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with fluclоxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Do not take Co-codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-codamol

Take special care and check with your doctor before taking Co-codamol if:
- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Have previously suffered withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- Feel you need to take more 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 you prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- You have severe kidney, liver or thyroid problems because the dose might need to be lower
- you are prone to suffer from asthma
- You have problems passing water or prostate problems.
- 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 anti-inflammatory drugs such as Ibuprofen.
- You are taking a benzodiazepine.
- If you know you are slow or intermediate metabolizer of enzyme called CYP2D6, because a different dose may be applicable to you.
- If you are taking medicine that induces CYP3A4 enzyme activity such as rifampicin.
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you have problems with your adrenal glands (Addison's disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)

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 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. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Sleep-related breathing disorders
Co-codamol 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.

Children and adolescents

Use in children and adolescents after surgery
Co-codamol should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome. They may be at increased risk of severe side effects in case of morphine toxicity

Use in children with breathing problems
Co-codamol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children. If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Co-codamol
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Co-codamol can affect the way some other medicines work. Also, some other medicines can affect the way Co-codamol works. 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, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine, and tell your doctor, if you 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, tranylcypramine

Tell your doctor or pharmacist if you are taking any of the following medicines, or have taken them in the past two weeks:
- Medicines which make you drowsy or sleepy (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.
- Anti-depressant medicines such as imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine.
- Anti-histamine medicines used to treat allergies

Tell your doctor or pharmacist if you are taking any other medicines:
- Medicines used to thin the blood such as warfarin.
- Chloramphenicol - an antibiotic used for infections.
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine - for lowering blood cholesterol levels.
- The oral contraceptive pill.
- Medicines such as quinidine, fluoxetine, paroxetine, bupropion, cinacalcet, methadone or rifampicin, as they may alter the effect of Co-codamol.
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- phenothiazines (medicines that calm your mood) or tricyclic antidepressants
- antihypertensive drugs, diuretics (water pills)
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- patients should not take any other paracetamol containing medicines whilst taking Co-codamol. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Co-codamol can interfere with some laboratory tests used for determining some diseases.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-codamol.

Talk to your doctor or pharmacist if you experience any of the following symptoms while using Co-codamol
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Taking Co-codamol food and drinks
You should not drink alcohol while you are taking these tablets.
This is because taking Co-codamol can change the way alcohol affects you.

Pregnancy and breast-feeding
Do not take Co-codamol and Talk to your doctor before taking these tablets:
- You are pregnant, think you may be pregnant or plan to get pregnant
- You are planning to breastfeed
- Do not take Co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.
- as they can affect the baby and can cause breathing problems when the baby is born.

Driving and using machines
Co-codamol can affect your ability to drive as it may make you sleepy or dizzy
- Do not drive whilst 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 whilst taking this medicine

Changing or stopping treatment
Chronic usage of Co-codamol may lead to tolerance and dependence. If you have taken regular daily doses of Co-codamol for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

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 Co-codamol 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 Co-codamol 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 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 Co-codamol).

3. How to take Co-codamol

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

Your prescriber should have discussed with you, how long the course of Co-codamol will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.
Always take Co-codamol exactly as your doctor has told you. 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 Co-codamol, 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 Co-codamol).
- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to
- Swallow the tablets whole with a drink of water

Adults: 2 tablets every 4 to 6 hours up to a maximum of 8 tablets in 24 hours. Elderly people may be prescribed a lower dose.
If you feel the effect is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist. 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.
A lower dosage may be needed if you are elderly or have other medical problems.
Check with your doctor about this.
Do not take with any other paracetamol-containing products.

Use in children aged 16 to 18 years: 1-2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Use in children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of 4 tablets 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.

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

If you take more Co-codamol than you should
- Talk to a doctor at once if you take too much of this medicine 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 do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

If you stop taking Co-codamol
You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. If you suddenly stop taking these tablets you may get withdrawal symptoms such as, agitation, anxiety, palpitations, shaking or sweating.

Co-codamol should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Important side-effects you should know about Co-codamol
- 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 taking the tablets.

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

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

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:
- Constipation
- Feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)
- Frequency "Not known" (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Other possible side effects:
- Not known (frequency cannot be estimated from the available data):

  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.

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 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 Co-codamol

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.

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. Do not throw away 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

Co-codamol 15mg/500mg:
- The active substance is Paracetamol and Codeine Phosphate. Co-codamol 15mg/500mg tablets contain 500mg of Paracetamol and 15mg of Codeine Phosphate hemihydrate per tablet
- The other ingredients are Pregelatinized maize starch, Stearic acid, Povidone K-30, Lactose monohydrate, Powdered cellulose, Talc, Magnesium stearate.

Co-codamol 30mg/500mg:
- The active substance is Paracetamol and Codeine Phosphate. Co-codamol 30mg/500mg tablets contain 500mg of Paracetamol and 30mg of Codeine Phosphate hemihydrate per tablet
- The other ingredients are Pregelatinized maize starch, Stearic acid, Povidone K-30, Lactose monohydrate, Powdered cellulose, Talc, Magnesium stearate.

What Co-codamol looks like and contents of the pack
Co-codamol 15mg/500mg tablets are white to almost white, capsule-shaped, biconves, bevelled edged tablets, with 'CCD' on one side and 'score line' on the other side.

Co-codamol 30mg/500mg tablets are White to almost white, capsule-shaped, flat, bevelled edged tablet. The tablet is debossed with 'CCI' on one side and 'score line' on the other side.

Co-codamol 15mg/500mg tablets are available in cartons containing 30, 50 and 100 tablets in blisters. They are also available in bottle containing 100 tablets. Each carton contains one bottle.

Co-codamol 30mg/500mg tablets are available in cartons containing 30, 50 and 100 tablets in blisters. They are also available in bottle containing 100 and 250 tablets. Each carton contains one bottle.

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(1)

Size: 130x580 mm

Back Panel

130 mm

580 mm

(2)

Size: 130x580 mm