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Package leaflet: Information for the user

CO-CODAMOL 8MG/500MG TABLETS
(Codeine phosphate and 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, pharmacist or nurse.
- 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
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

This medicine has been prescribed for you to relieve from pain. It contains the codeine which belongs to a class of medicines called opioids, which are ‘pain relievers’. It also contains paracetamol, another analgesic to relieve pain. 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. 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 Tablets

Important information:

- 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 regularly for headaches too often or for too long can make them worse.

Do not take these tablets:

- if you are allergic to paracetamol or codeine phosphate or any of the other ingredients of this medicine (listed in section 6)
- 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 caused by poisoning or severe bloody diarrhoea (pseudomembranous colitis)

- if you have difficulty breathing, or other chronic lung disease
- if you are having an asthma attack.
- if you are a child under 12 years of age

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine. Take special care with this medicine if you have:

- liver or kidney problems (especially if severe)
- diseased adrenal glands (Addison’s disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
- inflammatory bowel disease
- gall bladder disease or gall stones
- recently had surgery on your gastro-intestinal tract or urinary system
- an enlarged prostate gland and have difficulty urinating and are male
- epilepsy or suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- an underactive thyroid gland
- if you have a condition called myasthenia gravis which weakens the muscles.
- low blood pressure or are in shock
- suffered from mental illness.
- 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 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 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.

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.

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.

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.

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 ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Co-codamol, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn’t help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’)

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Co-codamol).

During treatment with Co-codamol, tell your doctor straight away if:

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

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.

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.

Other medicines and Co-codamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect Co-codamol:

- ciprofloxacin, isoniazid (antibacterial medicine)
- diflunisal (pain killer)
- probenecid (used to treat gout)
- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide)
- oral contraceptives (the “pill”)
- medicines to prevent blood clotting such as warfarin
- cyclizine, metoclopramide or domperidone (to prevent sickness)
- guanethidine or diuretics (“water tablets”) e.g. spironolactone, furosemide (to treat high blood pressure)
- mexiletine (to treat irregular heartbeats)
- loperamide or kaolin (to treat diarrhoea)
- selegiline (for Parkinson’s disease)
- phenytoin (to treat epilepsy)
- cimetidine (to treat stomach ulcers)
- atropine or hyoscine (anticholinergic medicines)
- cisapride (to treat gastro-oesophageal reflux disease)
- medicines which affect the nervous system such as sleeping tablets, diazepam, hydroxyzine and medicines to treat mental illness such as chlorpromazine and haloperidol
- medicines to treat depression (e.g. tranylcypromine, amitriptyline)
- medicines which affect the liver (e.g. primidone and rifampicin)
- colestyramine (to treat high cholesterol levels)
- muscle relaxants
- barbiturates (e.g. phenobarbital)
- anaesthetics
- opioid antagonists (buprenorphine, naltrexone, naloxone)
- 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)
- 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.

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

If you go into hospital for surgery or tests, tell your doctor you are taking Co-codamol, as you may interact with some anaesthetics and influence the results of certain tests and diagnostic procedures.

Co-codamol tablets with food, drink and alcohol

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If your diet is poor or you have a low protein intake, you may be at a higher risk of serious paracetamol poisoning when taking Co-codamol tablets. Drinking alcohol whilst taking co-codamol may result in drowsiness, difficulties in breathing, coma and may be life-threatening. It is recommended not to take alcohol while you are taking this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take co-codamol 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 co-codamol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

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

Driving and using machines

Co-codamol may cause dizziness, blurred vision or the inability to think clearly. Make sure you are not affected before you drive or operate machinery.

- 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 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.

Co-codamol tablets contain Benzoates

- This medicine contains parahydroxybenzoates (E218-Methyl para hydroxy benzoate, E216-Propyl para hydroxy benzoate, E214-Ethyl para hydroxy benzoate), which may cause allergic reactions (possibly delayed).

3. How to take Co-codamol Tablets

Always take this medicine exactly as your doctor or pharmacist 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).

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.

The recommended dose is:

Adults over 18 years:

- The recommended dose is one or two tablets to be swallowed with water.
- The dose should not be taken more frequently than every 4-6 hours and not more than 4 times in any 24 hour period.
- The maximum daily dose is 8 tablets (4g of paracetamol and 64mg of codeine phosphate) in any 24 hour period in divided doses.

Children aged 16 years to 18 years:

Children aged 16 years or above should take one or two tablets every 6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children aged 12 years to 15 years:

The recommended dose for children aged 12 years to 15 years is 1 tablet every 6 hours when needed. Do not take more than 4 tablets in 24 hours.

Children aged less than 12 years:

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

Elderly: Dosage is usually reduced in the elderly with liver damage.

Do not exceed the stated dose.

If you take more Co-codamol Tablets than you should

Talk to your 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. 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, loss of appetite, stomach pain or liver damage, coma, pale or clammy skin, fits, confusion, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow heart beat or breathing rate.

If you stop taking Co-codamol 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. Contact your doctor for advice on how to stop taking Co-Codamol tablets gradually to avoid withdrawal symptoms.

If you forget to take Co-codamol Tablets

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

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible Side Effects

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

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

Very rare (may affect up to 1 in 10,000 people):

- A severe skin reaction, such as reddening of the skin with blisters or peeling and may be associated with a high fever and joint pain. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome or toxic epidermal necrolysis), or if you experience a red, scaly rash with bumps under the skin and blisters (acute generalised exanthematous pustulosis or fixed drug eruption).

Not known (frequency cannot be estimated from the available data):

- Swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing, increased sweating, redness or flushed face, mucosal lesions (such as mouth ulcers), drug fever. 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.
- severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis).
- a fit (seizure)
- difficulty breathing and you feel dizzy
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

Uncommon (may affect up to 1 in 1,000 people)

- kidney failure (fluid retention, shortness of breath, tiredness, confusion)

Not known (frequency cannot be estimated from the available data):

- dependence and addiction (see section "How do I know if I am addicted?")
- constipation, feeling sick (nausea), being sick (vomiting), dry mouth
- dizziness, spinning sensation, drowsiness, confusion, light-headedness
- feeling overly happy (euphoria)
- a feeling of unease or dissatisfaction
- a less frequent or difficulty in needing to pass urine, kidney problems
- you get infections or bruise more easily than usual. This could be because of a blood problem.
- stomach irritation (mild stomach pain, heartburn and feeling sick), loss of appetite, dry mouth, difficulty in the passage of food through guts, abdominal pain and swelling (may be signs of liver damage, biliary spasm or a swollen intestine)
- slow heart rate, palpitations, low blood pressure, inflammation of the heart muscle
- a less frequent need to pass urine, kidney problems
- mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, difficulty sleeping, nightmares, reduced alertness, tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, difficulty sleeping, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)
- blurred or double vision, excessive constriction (shrinking) of the pupil of your eye
- lower abdominal pain (may be caused by spasms of the uterus)
- trembling, unusual tiredness or weakness, general discomfort and illness, low body temperature
- problem affecting a valve in the intestines (sphincter of Oddi dysfunction)

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.

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 Co-codamol Tablets

- Keep this medicine out of the sight and reach of children.
- 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.
- Do not store above 25°C. Store in the original package.
- Do not use these tablets after expiry date shown 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 Co-codamol Tablets contain

- The active substances are 8 mg Codeine phosphate and 500 mg Paracetamol
- The other ingredients are: maize starch, potato starch, povidone, stearic acid, talc, magnesium stearate, methyl-p-hydroxybenzoate (E218), ethyl-p-hydroxybenzoate (E214) and propyl-p-hydroxybenzoate (E216).

What Co-codamol Tablets look like and contents of the pack

- The tablets are white to off-white, capsule shaped biconvex tablets, scored on one side and plain on the other side.
- They are available in packs of 48, 50, 96 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address:
Bristol Laboratories Ltd,
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Telephone:0044 (0)1442 200922
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Manufacturer

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United Kingdom

Co-codamol 8 mg/500 mg Tablets; PL 17907/0163

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