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Package leaflet: Information for the user

**CO-CODAMOL
8MG/500MG TABLETS
(Cocaine phosphate and Paracetamol)**

Important things you should know about Co-codamol

- This medicine can only be used for the short-term treatment of acute moderate pain when other painkillers have not worked. Do not take less than four hours after taking other painkillers.
- You should only take this product for a maximum of 3 days at a time. If you need to take it for longer than 3 days you should see your doctor or pharmacist for advice.
- This medicine contains cocaine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than 3 days it can make them worse.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after three days.

What is in this leaflet:

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

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

- Co-codamol tablets contain a combination of two ingredients paracetamol and cocaine phosphate. Paracetamol is a non-narcotic analgesic (pain killer). This product contains cocaine. Cocaine belongs to a group of medicines called opioid analgesics which act to relieve pain. Cocaine can be used on its own or in combination with other painkillers such as paracetamol. Co-codamol is used for the short-term treatment of acute moderate pain caused by headaches, migraine, toothache, neuralgia, period pain and rheumatic pains when other painkillers have not worked. Wait at least 4 hours after you last took other painkillers before taking this medicine.
- Co-codamol can be used in adults and 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

- This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.
- This medicine contains cocaine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it (see "If you stop taking Co-codamol tablets").
- If you take a painkiller for headaches for more than 3 days it can make them worse.

Do not take Co-codamol:

- if you are allergic to paracetamol or cocaine phosphate or any of the other ingredients of this medicine (listed in section 6)
- if the person going to take the tablets under 12 years of age. Co-codamol must not be given to children under 12 years of age.
- 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
- for pain relief in children and adolescents (under 18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you know that you metabolise very rapidly cocaine into morphine
- if you are breastfeeding
- 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, Tranylcypromine

Warnings and precautions

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

- kidney or liver problems
- are taking alcohol or aspirin
- suffer from seizures
- diagnosed 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 gastrointestinal 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 pain/tears, 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 alcoholism, drug abuse or dependence or mental illness.

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.

Cocaine 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 cocaine 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.

- 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 while 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 illness, 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 fluclxacillin (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 fluclxacillin. Symptoms of metabolic acidosis may include serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Children and adolescents

Co-codamol must not be given to children under 12 years of age.

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, (may be seen in children with neuromuscular disorders, severe heart or lung conditions, severe respiratory or lung infections, multiple trauma or after extensive surgical procedures) since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Co-codamol

This medicine contains paracetamol.

Do not take with any other paracetamol containing products.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines in the past two weeks.

The following medicines can affect Co-codamol:

- Medicines which make you drowsy or sleepy (e.g. CNS depressants or benzodiazepines) such as other pain relievers, sleeping tablets, cough medicines, anaesthetics, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety, high blood pressure or anaesthetics.
- Anti-depressant medicines (e.g. imipramine, amitriptyline, tranylcypromine, doxepin, mirtazapine (tricyclic) or chlorpromazine (phenothiazines))
- ciprofloxacin, isorizid (antibacterial medicine)
- difenhydramine (painkiller)
- probenecid (used to treat gout)
- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide)
- oral contraceptives (the "pill")
- guanethidine or diuretics ("water tablets") e.g. spironolactone, furosemide (to treat high blood pressure)
- metaxalone (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
- medicines which affect the liver (e.g. paracetamol and tramadol)
- muscle relaxants
- barbiturates (e.g. phenobarbital)
- opioid antagonists (buprenorphine, nalbexone, naloxone)
- Medicines used to thin the blood (e.g. warfarin).
- Mesoclonamide or domperidone (used to stop you feeling sick (nausea) or being sick (vomiting)).
- Colchicine (for lowering blood cholesterol levels).
- fluclxacillin (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 recommendations 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.

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

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diagnostic procedures.**Cocodamol tablets with food, drink and alcohol**

- 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 Cocodamol tablets.
- Drinking alcohol whilst taking cocodamol may result in drowsiness, difficulties in breathing, coma and may be life-threatening. It is recommended not to take alcohol while you are taking Cocodamol tablets.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

Do not take Cocodamol tablets during pregnancy, unless advised by your doctor. Regular use during pregnancy may cause breathing problems and withdrawal symptoms in the newborn.

Breast-feeding

Do not take Cocodamol while you are breastfeeding. Codeine and morphine pass into breast milk.

If necessary, paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Driving and using machines

Cocodamol 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.

Cocodamol tablets contain Benzocaine

This medicine contains ethyl hydroxybenzoate (E214), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

3. How to take Cocodamol Tablets

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

Cocodamol should be used for the 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.

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 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:

Cocodamol should not be given to children below the age of 12 years, due to the risk of severe breathing problems. Do not take for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.

Elderly:

Dosage is usually reduced in the elderly with liver damage.

If you stop taking Cocodamol tablets

This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms such as tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

Do not exceed the stated dose. If symptoms persist consult your doctor.

If you take more Cocodamol Tablets than you should

Seek immediate medical advice in the event of an overdose, even if you feel well, because of the risk of 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, coma, pale skin, low blood pressure, pinpoint pupils, irregular slow or fast heartbeat, liver or kidney damage or difficulty breathing.

If you forget to take Cocodamol 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. Remember to leave at least 4 to 6 hours between doses for adults and 6 hours for children aged 12 to 18 years.

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 this medicine and seek immediate medical help if you experience any of the following serious side effects:

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

- 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 (severe generalised exanthematous pustulosis or fixed drug eruption).
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis).

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, rashes which are itchy or lumpy (hives), or nettle rash (urticaria). This may mean you are having an allergic reaction to this medicine.
- Fits (seizures).
- Difficulty breathing and dizziness.
- 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:

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

- Constipation, feeling sick (nausea), being sick (vomiting), dry mouth
- Dizziness, light-headedness, drowsiness, confusion
- Pain and difficulty passing urine
- Infections or bruising more easily than usual. This could be because of a blood problem
- Feelings of unease or dissatisfaction, overwhelming feeling of happiness and well-being, restlessness, irritability, headache, excessive drowsiness or sleeping
- Excessive constriction (shrinking) of the pupil of your eye and drooping eyelid
- Tolerance (medicine has less effect) or dependence (sufferer with withdrawal symptoms if you stop, difficulty sleeping, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly).

Other side effects:

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

- Gastrointestinal system – stomach irritation (mild stomach pain, heartburn and feeling sick), loss of appetite, difficulty in the passage of food through guts, abdominal pain and swelling may be signs of liver damage or a swollen intestine
- Heart – slow heart rate, palpitations, low blood pressure, inflammation of the heart muscle
- Urinary system – a less frequent need to pass urine, kidney problems
- Nervous system – mood changes, depression, hallucinations (seeing or hearing things that are not real), excitation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, difficulty sleeping, nightmares, reduced alertness
- Eyes – blurred or double vision
- Reproductive system – lower abdominal pain (may be caused by spasm of the uterus)
- Others – trembling, unusual tiredness or weakness, general discomfort and illness, low body temperature
- Problem affecting a valve in the intestines (sphincter of Oddi dysfunction)

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 Cocodamol 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 Cocodamol Tablets contain**

- The active substance is codeine phosphate and 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 Cocodamol 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 8, 10, 12, 16, 20, 24, 28, 30 and 32 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address:
Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamstead, Hertfordshire, Herts, UK
Telephone 0044 (0) 1442 209922
Email: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Limited
Laporte Way, Luton, LU14 8WL,
United Kingdom

Cocodamol 8 mg/500 mg Tablets, Pl. 17907062

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