PATIENT INFORMATION LEAFLET
CO-CODAMOL EFFERVESCENT TABLETS 8/500mg

The name of this medicine is Co-codamol Effervescent Tablets 8/500mg, which will be referred to as Co-codamol 8/500 throughout this leaflet.

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 or pharmacist has told you.

- This medicine can only be used for the short-term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days, you should see your doctor or pharmacist for advice.
- **This medicine contains codeine which can cause addiction if you take it continuously for more than three 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 three days, it can make them worse.**
- 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 or pharmacist. 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:

1. What Co-codamol 8/500 is and what it is used for
2. What you need to know before you take Co-codamol 8/500
3. How to take Co-codamol 8/500
4. Possible side effects
5. How to store Co-codamol 8/500
6. Contents of the pack and other information

1. WHAT CO-CODAMOL 8/500 IS AND WHAT IT IS USED FOR

Co-codamol is an analgesic (painkiller), 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 tablets 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. This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-CODAMOL 8/500

- **This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.**
- **This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.**
- **If you take a painkiller for headaches for more than three days, it can make them worse.**

Do not take Co-codamol 8/500 if you:

- know that you metabolise very rapidly codeine into morphine
- are breast feeding
- have diarrhoea caused by poisoning until the toxic material has been eliminated, or have severe bloody diarrhoea
- are a child or adolescent for pain relief (0-18 years of age) after removal of your tonsils or adenoids due to obstructive sleep apnoea syndrome
- are a child under the age of 12 years old
- are **allergic** to **paracetamol, codeine, other opioids** or any of the other **ingredients in the tablets** (listed in Section 6)
- have a **dependency to alcohol**
- have **difficulty breathing, obstructive airways disease** or **other chronic lung disease**
- are having an **asthma attack**
- have **bowel problems**
- have **raised pressure inside the skull or around the brain** or **head injury**
- **are taking medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have them taken in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine (see 'Other medicines and Co-codamol 8/500).**

Warnings and Precautions

Tolerance, dependance, 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 8/500 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 8/500 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 8/500, 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 8/500).

Talk to your doctor or pharmacist before taking Co-codamol 8/500 if you:

• have **liver or kidney problems.**
• suffer from **seizures.**
• have a condition called **myasthenia gravis** which weakens the muscles.

Also talk to your doctor or pharmacist before taking Co-codamol 8/500 if you:

- have an underactive thyroid gland
- have a disease or tumour of the Adrenal gland such as Addison's disease or high blood pressure caused by a tumour near a kidney (pheochromocytoma)
- are elderly
- feel weak, have low blood pressure or are in shock
- are already taking **other medicines containing paracetamol**
- are on a **low sodium diet**
- have an inflammatory bowel disease
- have a gall bladder disease or gall stones
- recently had surgery on your gastro-intestinal tract or urinary system
- have an enlarged prostate gland and have difficulty urinating and are male
- suffer from epilepsy or suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- suffer from alcoholism, drug abuse or dependence or mental illness

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. 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.

During treatment with Co-Codamol 8/500, tell your doctor straight away if:
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).

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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Co-codamol 8/500

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

Sleep-related breathing disorders
Co-codamol 8/500 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
Co-codamol must not be given to children under 12 years of age.
Use in children and adolescents after surgery: Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.
Use in children with breathing problems: Codeine is not recommended in children with breathing problems (may be seen in children with neuromuscular disorders, severe heart or lung conditions, upper 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 8/500
Do not take these tablets if you are already taking other medicines containing paracetamol. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may decrease or increase the effect of Co-codamol 8/500:

- Cyclizine, metoclopramide or domperidone (often taken for sickness or stomach problems)
- Cholestyramine (for high blood lipid levels)
- Anticoagulants to reduce blood clotting (e.g. warfarin)

- Ciprofloxacin (antibacterial medicine)
- 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)
- Dopaminergics e.g. Pethidine or Selegiline (for Parkinson's disease)
- Phenytoin (to treat epilepsy)
- Cimetidine (to treat stomach ulcers)
- Ethyl alcohol
- Oral steroid contraceptives
- Atropine or hyoscine (anticholinergic medicines)
- Cisapride (to treat gastro-oesophageal reflux disease)
- Medicines which affect the liver (e.g. primidone and rifampicin)
- Muscle relaxants
- Barbiturates (e.g. Phenobarbital)
- Anaesthetics
- Neuromuscular blocking agents
- Opioids 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).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking or have taken within the last two weeks:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression
- medicines which make you drowsy or sleepy (CNS depressants and benzodiazepines) such as medicines used to treat anxiety or anaesthetics.
- medicines for depression such as dosulepin, mirtazapine (Tricyclic) or chlorpromazine (phenothiazines)
    - medicines known as tranquillisers, or hypnotics
    - sleeping tablets, sedatives and some antihistamines
    - gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

You may experience more drowsiness if you take these medicines with co-codamol. Concomitant use of Co-codamol and sedative medicines such as benzodiazepines or related drugs also increases the risk of 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

Diet
If your diet is poor or you have low protein intake, you may be at a higher risk of serious paracetamol poisoning when taking Co-codamol tablets.

It may still be all right for you to take Co-codamol 8/500 and your doctor will be able to decide what is suitable for you.

Taking your medicine with food and drink:
Co-codamol 8/500 should be dissolved in at least half a glass of water and can be taken with or without a meal.

Co-codamol and alcohol:
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 Co-codamol.

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

Pregnancy:
Do not take Co-codamol tablets during pregnancy, unless advised by your doctor. Regular use during pregnancy may cause withdrawal symptoms in the newborn.

Breast-feeding:
Do not take codeine while you are breast-feeding. Codeine and morphine pass into breast milk.

Driving and using machinery
Co-codamol tablets may cause dizziness, blurred vision or the inability to think clearly.
Make sure you are not affected before you drive or operate machinery.
This 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:
  - this medicine has been prescribed to treat a medicinal 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 8/500 contains sodium and aspartame
The maximum recommended daily dose of this medicinal product contains 3504mg sodium (found in table salt). This is equivalent to 175% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need Co-codamol 8/500 on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

This medicine contains 5mg aspartame in each effervescent tablet.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. HOW TO TAKE CO-CODAMOL 8/500

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Co-codamol 8/500, 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 8/500).
Do not take for more than three days. If you need to use this medicine for more than three days, you must speak to your doctor or pharmacist. Co-codamol 8/500 should be used for 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.

Dosage:
The usual doses for Co-codamol 8/500 are as follows:

Adults:
Should take one or two tablets dissolved in water every 6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children 16-18 years:
One or two tablets dissolved in water every 6 hours when necessary to a maximum of 8 tablets in 24 hours.

Children 12-15 years:
One tablet dissolved in water every 6 hours when necessary. Do not take more than 4 tablets in 24 hours.

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

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. Do not exceed the recommended dose.
Co-codamol 8/500 should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Method of Administration
For oral administration only. These tablets should be dissolved in at least half a glass of water before taking them. The solution should be drunk immediately after preparation.
These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Co-codamol 8/500 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.
Remember to take the pack and any remaining tablets with you. If you are giving this medicine to a child, immediate medical advice should be sought in the event of overdose, even if the child seems well, because of the risk of delayed, serious liver damage.
Symptoms of an overdose include feeling or being sick, loss of appetite, stomach pain, coma, pale skin, low blood pressure, pinpoint pupils, fast heartbeat or difficulty breathing.

If you forget to take Co-codamol 8/500
If you forget to take one or more doses, take your next dose when you remember and then go on as prescribed.
Do not take a double dose to make up for a forgotten dose. Remember to leave at least 6 hours between doses for adults and 6 hours for children aged 12 to 18 years.

If you stop taking Co-codamol 8/500
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.
You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms such as tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol 8/500 can cause side effects although not everybody gets them.
Stop taking Co-codamol and see a doctor or go to hospital straight away if:
Very rare (may affect up to 1 in 10,000 people):

- You get 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)
- Severe stomach pain, which may reach through 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, 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.
- Fits (seizures).
- Difficulty breathing and dizziness.

Tell your doctor or pharmacist if any of the following side effects get 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**
- **You get infections or bruise more easily. This could be because of a blood problem.**
- **Feeling of unease or dissatisfaction, overwhelming feelings 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 (suffer from withdrawal symptoms e.g. tremor, difficulty sleeping, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling being sick if the medicine is stopped too quickly).**

Other side effects:

- **Gastrointestinal system** - stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, being sick, loss of appetite, dry mouth, 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), restlessness, somnolence, excitation, 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).
- **Eyes** - blurred or double vision, extremely small pupils.
- **Reproductive system** - lower abdominal pain (may be caused by spasms of the uterus).
- **Others** - trembling, unusual tiredness or weakness, general discomfort and illness, low body temperature.
- **Skin** - Very rare cases of serious skin reactions have been reported.
- **Respiratory** - Respiratory depression.
- **Psychiatric** - dysphoria, euphoria.
- **Hepatobiliary** - problem affecting a valve in the intestines (sphincter of Oddi dysfunction) (frequency not known)

An adverse reaction with an unknown frequency may also occur:

- **A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).**

How do I know if I am addicted?
If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you, it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- When you stop taking the medicine you feel very unwell, but you feel better if you start taking the medicine again.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CO-CODAMOL 8/500

Do not store your tablets above 25°C. Store in a dry place and protect from light. Do not take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.
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.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-codamol Effervescent Tablets 8/500mg contain:
The active ingredients are paracetamol and codeine phosphate hemihydrate. Each tablet contains 500mg paracetamol and 8mg codeine phosphate hemihydrate. The other ingredients are sodium hydrogen carbonate, citric acid anhydrous, sodium carbonate, povidone, simeticone, sodium saccharin, aspartame (E951) and polysorbate 80.

What Co-codamol Effervescent Tablets 8/500mg look like and the contents of the pack:
Co-codamol Effervescent Tablets 8/500mg are white, circular, with a flat bevelled edge and plain on both sides.
Your medicine is available in blister packs of 7, 10, 14, 28, 30 and 32 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder:
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release:
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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