

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

The name of this medicine is Co-Codamol Effervescent Tablets 8/500 mg, 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.

- 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.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Co-codamol 8/500 are and what they are 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 ARE AND WHAT THEY ARE USED FOR

The active ingredients in Co-codamol 8/500 are paracetamol and codeine phosphate hemihydrate. Codeine can be used in children over 12 years of age for short-term relief of moderate pain that is not relieved by paracetamol, ibuprofen or aspirin alone. It can be used on its own or in combination with other pain killers. It is used to relieve muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache and period pains. Do not take less than four hours after taking other painkillers.

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

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**

Warnings and Precautions

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

- have an under-active 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)
- have a condition which weakens the muscles called myasthenia gravis
- are elderly
- feel weak, have low blood pressure or are in shock
- are already taking **other medicines containing paracetamol**
- have **liver or kidney problems**
- 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.

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, since the symptoms of morphine toxicity may be worse in these children.

Taking other medicines

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)
- colestyramine (for high blood lipid levels)
- anticoagulants to reduce blood clotting (e.g. warfarin)
- MAOI's (e.g. moclobenide)
- Medicines which affects the nervous system such as sleeping tablets, diazepam, hydroxyzine and medicines to treat mental illness
- Medicines to treat depression (e.g. tranylcypromine, amitriptyline)
- 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)
- Dompaminergics 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
- Hypnotics, anxiolytics, antipsychotics,
- Neuromuscular blocking agents
- Opioids antagonists (buprenorphine, naltrexone, naloxone)

Concomitant use of Co-Codamol and 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

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. Do not drink alcohol whilst 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.

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.

Do not take codeine while you are breast feeding. Codeine and morphine passes into breast milk.

Pharmacode

Pharmacode

Customer: Kent Pharma **Originated by:** DOB Colours: Black
Product: Co-Codamol Effervescent Tablets 8/500mg (PL 20417/0028)
Dimensions: 500 x 210mm
Item Code: BXP028FUL
Proof No and Date: 1 20/03/2020
Revision: Removal of Fannin as batch release site
ARTWORK FOR SUBMISSION
Supersedes: BXP028FUK P2

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.

Important information about some of the ingredients of Co-codamol 8/500

Each of these tablets contains about 438 mg of sodium and may interfere if you are on a **low sodium diet**. Talk to your doctor or pharmacist if you need one or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

This product also contains **aspartame** (a source of phenylalanine), which should not be given to anyone with **phenylketonuria**.

3. HOW TO TAKE 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.

Dosage

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

Adults:

Should take 1 or 2 tablets dissolved in water every 6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children 16-18 years:

One to 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. 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.

Withdrawal symptoms: 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 about this product 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:

- You get 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 or nettle rash (hives). This may mean you are having an allergic reaction to Co-Codamol.
- 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)

Talk to your doctor straight away, if you notice any of the following serious side effects:

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

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

- **Constipation, feeling sick (nausea), being sick (vomiting)**
- **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.**

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, 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)
- **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

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. **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 8/500 mg Effervescent Tablets 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 8/500 look like and the contents of the pack:

Co-codamol 8/500 mg Effervescent Tablets 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, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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