

Package leaflet: Information for the user

CO-CODAMOL 8MG/500MG TABLETS
(Codeine 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 codeine 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 or pharmacist 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 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 Tablets are and what they are 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 are and what they are used for

- Co-codamol tablets contain a combination of two ingredients paracetamol and codeine phosphate. Paracetamol is a non-narcotic analgesic (pain killer) This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Codeine can be used on its own or in combination with other pain killers such as paracetamol.
- Codeine 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. It can be used to relieve pain caused by headache, migraine, toothache, period pain, muscular pains and backache.

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

- This medicine contains codeine 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 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 codeine phosphate or any of the other ingredients of this medicine (listed in section 6)
- 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 (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you know that you metabolise very rapidly codeine into morphine
- if you are breast-feeding.

Warnings and precautions**Take special care with this medicine and talk to your pharmacist or doctor if you have:**

- kidney or liver problems
- 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
- muscle weakness (myasthenia gravis)
- low blood pressure or are in shock
- suffered from alcoholism, drug abuse or dependence or mental illness.

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**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**! 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.

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
- 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)

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

- Do NOT drink alcohol whilst taking Co-codamol Tablets.

Pregnancy, breast-feeding and fertility

- Do not take this medicine if you are pregnant, think you have become pregnant or intend to become pregnant whilst taking these tablets.
- Do not take Co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.

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 ethyl hydroxybenzoate (E214), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), which may cause allergic reactions.

3. How to take Co-codamol Tablets

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

The recommended dose is:

Adults over 18 years:

- The usual 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 12 years to 18 years:

Children aged 12 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 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.

- 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.

If you stop taking Co-codamol 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. 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 Co-codamol Tablets than you should

Contact your nearest hospital A&E (casualty department) or your doctor immediately. Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

Signs of overdose include difficulty in breathing; pupils may be pin-point in size, nausea, vomiting, loss of appetite and abdominal pain.

If you forget to take Co-codamol Tablets

If you forget to take a dose, wait and take your next dose as usual.

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

4. Possible Side Effects

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

STOP taking and contact your doctor or go to a hospital straight away if you suffer from below conditions:

- **Allergic Reactions** – skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face, mucosal lesions (such as mouth ulcers), drug fever.
- Very rare cases of serious skin reactions have been reported.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Gastrointestinal system** - stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, feeling or being sick, loss of appetite, dry mouth, difficulty in the passage of food through guts, abdominal pain (may be caused by spasm of the bile ducts) and inflammation of the liver or pancreas
- **Heart** - slow heart rate, palpitations, low blood pressure, inflammation of the heart muscle
- **Blood** - anaemia, changes in numbers and types of blood cells. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor
- **Urinary system** - pain and difficulty in passing urine and a less frequent need to do so, kidney problems.

- **Nervous system** - confusion, drowsiness, dizziness, 'spinning' sensation, 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
- **Others** - trembling, unusual tiredness or weakness, malaise, low body temperature

Reporting of side effects

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

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 to talk to your doctor-

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

5. How to store Co-codamol Tablets

- Keep this medicine out of the sight and reach of children.
- 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 substance is codeine phosphate and paracetamol
- The other ingredients are: maize starch, potato starch, povidone, stearic acid, talc, magnesium stearate, methyl-p-hydroxy benzoate (E218), ethyl-p-hydroxy benzoate (E214) and propyl-p-hydroxy benzoate (E216).

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

- The tablets are clean, white, bevelled edged, debossed with '8' and broken breakline on one side and 'BL' 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

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Co-codamol 8mg/500mg Tablets;
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