

**Patient Information Leaflet for
Co-Codamol 8mg/500mg Tablets**
(Codeine Phosphate and Paracetamol)

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.
- This medicine can only be used for the short term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.
- You should only take this product for a maximum of 3 days at a time. If you need to take it longer than 3 days, you should consult 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.

What is in this leaflet

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2. What you need to know before you take Co-Codamol 8mg/500 mg Tablets
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1. What Co-codamol tablet is and what it is used for

Co-Codamol is a type of painkiller that contains paracetamol and 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. Co-Codamol tablets are 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. For headache, migraine, toothache, period pains, rheumatic pains, muscle pains and backache.

2. What you need to know before you take Co-codamol 8mg/500mg Tablets

This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms (e.g. feeling restless and irritable) 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 8mg/500mg Tablets:

- If you are under 18 years old and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- If you know you may metabolise very rapidly codeine into morphine.
- If you are breastfeeding or planning to breast feed.
- If you are allergic to Paracetamol, to Codeine or any other similar painkillers such as dihydrocodeine, or to any of the other ingredients listed in section 6. Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.
- If you have liver disease or kidney failure.
- If you have asthma or other breathing difficulties.
- If you suffer from heart failure due to lung disease.
- If you have recently suffered a head or brain injury.
- If you are suffering from diarrhoea associated with colitis or due to any type of poisoning.
- If you suffer from alcohol dependency.
- The person going to take the tablet is under 12 years old. Co-codamol must not be given to children under 12 years old.

Do not take Co-Codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-codamol.

Warnings and Precautions

Take special care and check your doctor or pharmacist before taking Co-codamol if you:

- Have kidney or liver problems or alcoholic liver disease or a history of drug abuse.

- Suffer from high blood pressure or have an irregular heartbeat (slow or rapid).
- Have an under active thyroid gland or adrenal gland.
- Have urinary or prostate problems.
- Have recently had surgery on your stomach, suffer from gallstones, bowel disorders or abdominal pain or swelling.
- Have ever suffered from convulsions or emotional problems.
- Are suffering from any kind of shock.
- Suffer from muscle weakness (myasthenia gravis).

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cold. Some people have a variation of this enzyme that can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, which means it will not provide enough pain relief or relieve their cold. 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 and adolescents with breathing problems

Co-Codamol is not recommended in children with breathing problems, as 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:

- Metoclopramide or Domperidone (for sickness and digestive disorders).
- Colestyramine (to help control blood cholesterol levels).
- Cimetidine (to treat stomach ulcers).
- Cisapride (to treat heartburn).
- Quinidine or Mexiletine (to treat certain heart conditions).
- Naloxone or Naltrexone (to treat drug overdose or abuse).
- Chloramphenicol (to treat eye infections).
- Hydroxyzine (an antihistamine used to treat itching).
- Blood thinning medicines such as Warfarin.
- Medicines to treat diarrhoea.
- Diuretics or other drugs for high blood pressure.
- Antimuscarinics (used to treat Parkinson's disease).
- Antidepressants including those known as monoamine oxidase inhibitors (MAOIs), anti-anxiety drugs, sedative or hypnotic drugs.
- Anaesthetics
- Barbiturates (e.g. Phenobarbital)
- Any other paracetamol containing products
- This medicine also contains paracetamol. Do not take anything else containing paracetamol while taking this medicine
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins

circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Co-codamol tablets should not be taken by patients taking monoamine oxidase inhibitors (MAOI's, e.g. moclobemide) or within two weeks of stopping treatment.

Co-codamol may interfere with laboratory tests and you should inform your doctor if you have any tests scheduled.

Pregnancy, breastfeeding and fertility

Do not take Co-codamol tablets if you are pregnant or while breast-feeding. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Codeine and Morphine passes into breast milk.

Co-codamol should not be used during breastfeeding (See the 'Do not take Co-codamol 8mg/500mg Tablets' section

Driving and using machines

Co-codamol can affect your ability to drive as it can make you feel sleepy or dizzy.

- Do not drive whilst 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 been following the instructions on how to take the medicine given by the prescriber and the medicine does not affect your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it safe for you to drive whilst taking this medicine. Co-codamol tablets contain parahydroxybenzoates (E214, E216 and E218):

May cause allergic reactions (possibly delayed).

3. How to take Co-Codamol 8mg/500 mg 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.

Adults: Two tablets not more frequently than every 4- 6 hours when necessary, up to a maximum of 8 tablets in 24 hours

Elderly: As for adults, however a reduced dose may be required. The dose should not be repeated more frequently than every four hours for adults. Not more than 4 doses should be administered in any 24 hour period.

Children and Adolescents:

Children aged 16-18 years: take one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12 – 15 years: take one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

The dose should not be repeated more frequently than every six hours for children over 12 years. Not more than 4 doses should be administered in any 24 hour period.

Swallow the tablets with a glass of water.

Do not give the tablets to children under 12 years due to the risk of severe breathing problems.

Do not give the tablets for more than 3 days at a time unless your doctor tells you to.

Do not drink alcohol or take other Paracetamol containing products whilst taking these tablets.

If you take more Co-codamol Tablets than you should:

Talk to a doctor at once if you take too much of this medicine, even if you feel well because of the risk of delayed, serious liver damage. Take the container and any remaining tablets with you. Symptoms of overdose include loss of appetite (anorexia), nausea, diarrhoea, vomiting and abdominal pain.

If you forget to take Co-codamol Tablets:

If you miss a dose, do not take a double dose to make up for the missed dose.

If you stop taking Co-codamol Tablets

Taking Co-codamol for a long time may lead to tolerance and dependence. Do not increase the dose or suddenly stop treatment without discussing this with your doctor if you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

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

Serious side effects

If you experience any of these symptoms after taking this medicine go to the nearest hospital immediately:

- Allergic reactions which may be severe such as skin rashes and itching sometimes with swelling of the mouth or face or shortness of breath
- Skin rash or peeling, or mouth ulcers
- Fits (convulsions)
- Difficulty breathing. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising or bleeding, throat and mouth ulcers or bleeding gums accompanied by tiredness and flu like symptoms

Very rare cases of serious skin reactions have been reported.

Other side effects

- Nausea and vomiting
- Headache
- Hallucinations
- Sweating
- Flushing
- Loss of appetite
- Nightmares
- Dry mouth
- Vertigo
- Muscle twitches or stiffness
- Blurred or double vision
- Slow heart rate
- A fall in blood pressure on standing up (causing dizziness, light-headedness or fainting)
- Pounding heart
- Dizziness
- Depression
- Generally feeling unwell
- Problems in passing urine
- Stomach cramps
- Tiredness
- Blood disorders which increases the risk of bleeding and bruising and makes infections more likely
- Codeine can affect your bowels and can cause incontinence, constipation, a watery diarrhoea like leakage, stomach pains and rarely, blockage of the bowel.

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.

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 this medicine according to the instructions on the pack it is unlikely that you will become addicted to this 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.

5. How to store Co-Codamol 8mg/500 mg Tablets

Keep medicines out of the sight and reach of children.

Do not store above 25°C. Store in a dry place. Store in the original packaging to protect from light and moisture. Do not use this medicine after the expiry date which is stated on the packaging.

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 ingredients in Co-codamol tablets are Paracetamol 500mg and Codeine Phosphate 8 mg. The inactive ingredients are starch (maize and potato), povidone, talc, stearic acid, magnesium stearate, methyl p-hydroxybenzoate (E218), ethyl p-hydroxybenzoate (E214) and propyl p-hydroxybenzoate (E216).

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

They are white capsule shaped tablets, broken breakline and embossed with ac 500/8 on one side. The other side is plain.

MA Holder and Manufacturer:

Aspar Pharmaceuticals Ltd, Albany House, Acrewood Way, St Albans, AL4 0JY, United Kingdom. PL 08977/0012

Available in Pharmacy packs: 12, 16, 24, 25, 30 and 32 in blister strip or bottles.

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