

Patient Information leaflet

CO-CODAMOL TABLETS 8/500 mg

(Codeine Phosphate 8mg/Paracetamol 500mg)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet.You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.

1. WHAT CO-CODAMOL TABLETS 8/500 mg ARE AND WHAT THEY ARE USED FOR

Co-codamol 8/500mg Tablets contain paracetamol and codeine (painkillers), and are used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. For headache, toothache, period pain, arthritic and rheumatic pain. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Co-codamol tablets 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.

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

- 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 this medicine if you:

- are allergic (hypersensitive) to paracetamol, codeine phosphate, other opioid painkillers or any of the other ingredients of this medicine (listed in section 6)
- have moderate or severe kidney failure or liver disease
- have asthma or another lung disease which makes breathing difficult
- have increased pressure in the brain, e.g. following a head injury
- have diarrhoea associated with inflammation of the bowel or following poisoning
- are an alcoholic
- are at risk of paralysis of the intestine (paralytic ileus)
- are taking Monoamine Oxidase Inhibitors for depression or have taken them within the last 14 days
- know that you metabolise very rapidly codeine into morphine
- are breastfeeding.
- Do not use 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.

DO NOT TAKE WITH ANY OTHER PARACETAMOL OR CODEINE CONTAINING PRODUCTS.

Children and adolescents

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.

Warnings and precautions

Tell your doctor before you start to take this medicine if you:

- suffer from myasthenia gravis (muscle weakness and fatigue)
- have low blood pressure or are suffering from shock
- have a history of cardiac arrhythmias (erratic heartbeat)
- have thyroid or adrenal disease
- have mild kidney or liver disease
- have prostate or urinary problems e.g. difficulty passing water
- suffer from convulsions
- have a history of drug abuse or emotional instability
- suffer from bowel disease
- have recently had gastro-intestinal surgery
- are elderly or infirm
- have gall stones.

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.

Other medicines and Co-codamol

Talk to your doctor or pharmacist before you take this medicine if you are taking any of the following:

- sedatives, tranquillisers, antidepressants, sleeping tablets, or alcohol
- medicines used to treat water retention or high blood pressure
- medicines to treat mental illness (anti-psychotics)
- medicines to prevent blood clotting, such as warfarin
- medicines to treat diarrhoea, such as loperamide and kaolin
- muscle relaxants, such as atropine
- anaesthetics or other drugs used in surgery (such as neuromuscular blocking agents)
- medicines that affect the liver e.g. carbamazepine, phenobarbital, phenytoin (anti-epileptics) or rifampicin (antibiotic).
- naloxone or naltrexone (used to treat drug abuse or overdose)
- colestyramine (used to reduce cholesterol in the blood)
- quinidine or mexiletine (used to treat certain heart conditions)
- metoprolamide or domperidone (used to treat nausea and vomiting)
- cimetidine (used to treat stomach ulcers)
- cisapride (used to treat heart burn)
- hydroxyzine (an anti-histamine)
- probenecid (used to treat gout)
- isoniazid (used to treat tuberculosis).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Pregnancy and breast feeding

Do not take Co-codamol during pregnancy unless advised by your doctor.
Do not take Co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

- If these tablets make you feel drowsy, do not 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.

Tell the hospital staff, your doctor or dentist that you are taking these tablets before you have any treatment or operation, or before the appointment date if you are to have a blood or urine test.

3. HOW TO TAKE CO-CODAMOL TABLETS 8/500 mg

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Adults (including the elderly) and children over 12 years of age:** one or two tablets 4 times a day.
- Swallow the tablets with a glass of water.
- Do not take more often than every 4 hours.
- Do not take for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

DO NOT EXCEED THE STATED DOSE

Co-codamol should not be taken by children below the age of 12 years, due to the risk of severe breathing problems

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

If an overdose has been taken telephone your doctor immediately. If the doctor is not there, go to your local hospital casualty department. Take this leaflet and any remaining tablets with you.

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.

The hazard of overdose with paracetamol is greater in those with alcoholic liver disease.

Risk of addiction

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately or go to the nearest hospital casualty department if you have any of the following:

- symptoms of an allergic reaction (rare side effect), such as skin rash or hives, swelling of the lips, face or neck leading to severe difficulty breathing.
- inflammation of the pancreas which causes severe pain in the abdomen and back (very rare side effect)

Tell your doctor or pharmacist if any of the following gets worse or lasts longer than a few days:

Common side effects

- constipation
- confusion and drowsiness

Uncommon side effects

- nausea, vomiting, stomach cramps, anorexia
- diarrhoea, incontinence
- abdominal pain (may be caused by spasm of the bile or urinary ducts)
- skin rash, itching, sweating, facial flushing, low body temperature
- dry mouth, blurred or double vision, pin-point pupils
- malaise, tiredness, headache
- dizziness, vertigo, light-headedness
- slow or rapid heartbeat, palpitations, breathing difficulties, problems in passing urine
- low blood pressure, feeling faint on standing from a seated or lying position
- decreased libido or potency
- convulsions, hallucinations, nightmares, depression, anxiety, mood changes
- uncontrolled muscle movement or rigidity.

There have been a few reports of low blood cell counts (platelets and white cells) associated with paracetamol-containing products but these were not necessarily due to paracetamol.

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 this medicine you feel very unwell but you feel better if you start taking the medicine again.

5. HOW TO STORE THIS MEDICINE

Keep out of the sight and reach of children

Do not store above 25 °C. Store in a well-closed container in a dry place, protected from light.

Do not use after the expiry date printed on the pack.

Do not throw away any medicines via waste water 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 this medicine contains:

The active ingredients in each tablet are paracetamol 500mg and codeine phosphate hemihydrate 8mg.

The other ingredients are maize starch, povidone, colloidal silica, magnesium stearate and potassium sorbate (E202).

What this medicine looks like and contents of the pack:

Co-codamol Tablets 8/500mg are white, flat, round tablets with 'CO' and 'COD' on either side of a breakline on one side and plain on the other.

They are available in packs of 30 and 32 tablets.

Marketing Authorisation Holder and Manufacturer:

M & A Pharmachem Ltd, Bolton BL5 2AL, UK

Date of revision: March 2014

PP2317

	W/T NO: 213273	SPEC NO: 39259	CUSTOMER: M&A Pharmachem
	JOB TITLE: Co-Codamol Tablets 8/500mg		ITEM CODE: PP2317
	SIZE: 160 x 232.833 mm	PROOF VERSION: Two (19/03/2014)	
We ask you to check fully and sign below. Every care has been taken to ensure correctness. We cannot be responsible for mistakes if passed by you. Please mark clearly any changes you require and return the original visual to us.	COLOURS Black		CUSTOMER COMMENTS:
	ARTWORK PREPARED BY: SIGN:		ARTWORK READ / CHECKED BY SIGN:
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