

Package leaflet: Information for the patient

CO-CODAMOL 8 MG/500 MG EFFERVESCENT TABLETS

Codeine phosphate hemihydrate and paracetamol

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 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.

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. Content of the pack and other information

1. What Co-codamol 8/500 is and what it is used for

The active ingredients in Co-codamol 8/500 are paracetamol and codeine phosphate hemihydrate.

Co-codamol 8/500 is for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. It is used to relieve muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache, period pains, aches and pains.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It 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.

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 this medicine for headaches for more than three days it can make them worse.

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

- are **allergic to paracetamol, codeine** or any of the **other ingredients** of this medicine (listed in section 6).
- have a **dependency to alcohol**
- have **difficulty breathing or other chronic lung disease**
- are having an **asthma attack**
- have **bowel problems**
- have **raised intracranial pressure or head injury.**
- 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
- know that you metabolise very rapidly codeine into morphine
- are breastfeeding

Warnings and precautions

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

- are already taking **other medicines containing paracetamol including over-the-counter cold remedies.**
- have **liver or kidney problems**
- 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.

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.

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

Other medicines and Co-codamol 8/500

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription, as they may decrease or increase the effect of Co-codamol 8/500.

Do not take these tablets if you are already taking other medicines containing paracetamol.

- 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 and CNS depressants such as sleeping tablets, sedatives and some antihistamines.

If you are unsure about interactions with any other medicines, talk to your pharmacist.

Co-codamol 8/500 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 and breast-feeding

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

Although there is no evidence that these tablets cause any ill effects during pregnancy, your doctor should advise you about taking them if you are pregnant.

Do not take codeine when you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machinery

These tablets may make you feel dizzy or drowsy and if this happens 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.

Co-codamol 8/500 contains sodium and aspartame

Each of these tablets contains about 438 mg of sodium and may interfere if you are on a **low 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

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. Do not exceed the recommended doses.

Dosage

The usual dose for Co-codamol 8/500 is as follows:

- Adults over 18 years:

One to two tablets dissolved in water every 4 to 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

- Children aged 16 years to 18 years:

One to two tablets dissolved in water every 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

- Children aged 12 years to 15 years:

One tablet dissolved in water every 6 hours as needed.

Do not take more than 4 tablets in 24 hours.

Elderly:

Elderly people may be prescribed a lower dose.

This medicine should not be taken for more than 3 days. If the pain does not improve after days, talk to your doctor for advice.

Use in children

Co-codamol should not be given to children under 12 years of age due to the risk of severe breathing problems.

Method of Administration

For oral administration only. Co-codamol should be dissolved in at least half a glass of water. The resulting solution should be stirred well before oral administration. 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:

If you have accidentally taken more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack 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.

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.

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.

- If you get any of the following symptoms after taking these tablets, **you should contact your doctor immediately:**
- **Any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.**
- **An acute allergic reaction (anaphylaxis) or swelling of the skin**
- **Rarely pancreatitis (inflammation of the pancreas which may cause severe abdominal pain that can spread through to your back)**
- **Very rare cases of serious skin reactions such as a severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), and skin rash with blisters and fever (acute generalized exanthematous pustulosis (AGEP)).**

The following effects have been reported:

- Skin rashes
- Constipation
- Nausea, vomiting
- Light-headedness, dizziness
- Confusion
- Drowsiness
- Urinary retention

There have been very rare reports of blood problems, so if you notice unusual bleeding or you bruise easily or have more fevers or infections (such as sore throats) than usual tell your doctor as soon as possible.

Important side effects you should know about Co-codamol 8/500

- Taking a painkiller for headache too often or for too long can make them worse.
- Long-term usage of high doses of codeine + paracetamol can be rarely associated with sensorineural hearing loss.
- taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets

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, 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.

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.

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. Content 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, 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, 20, 28, 30 and 32 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer:

The Product Licence holder is Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

The manufacturers responsible for batch release:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

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This leaflet was last revised in 03/2018.