

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.

- 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.

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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 other painkillers such as paracetamol or ibuprofen alone. It can be used on its own or in combination with other pain killers. Co-codamol 8/500 is used to relieve pain, including muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache, sore throat, period pains, aches and pains, discomfort associated with influenza (flu), feverishness and feverish colds.

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. BEFORE YOU TAKE CO-CODAMOL 8/500

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
- are a child or adolescents 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 12 years old
- are **allergic (hypersensitive) to paracetamol, codeine** or any of the **other ingredients** in the tablets (these are listed in Section 6, Further Information)
- are already taking **other medicines containing paracetamol**
- have a **dependency to alcohol**
- suffer from **acute asthma or other lung disease**
- have **raised intracranial pressure or head injury**
- are on a **low sodium diet**
- have **bowel or prostate problems**
- are receiving **monoamine oxidase inhibitor (MAOI) therapy**

Talk to your doctor if you:

- have **liver or kidney problems**

Take special care with Co-codamol 8/500 if you:

- have an under-active thyroid gland
- have a disease of the Adrenal gland called Addison's disease
- have a condition which weakens the muscles called myasthenia gravis
- are elderly
- feel weak
- are debilitated

Do not take for longer than directed by your doctor or pharmacist.

Taking codeine regularly for a long period of time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

Taking a painkiller for headaches too often or for too long can make them worse.

Warnings and Precautions

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: 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:

- 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

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.

Driving and using machinery

These tablets may make you feel dizzy or drowsy. If this happens do not drive or operate machinery.

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 exceed the recommended doses. If painful symptoms are not relieved in a few days, consult your doctor.

Dosage

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

Adults

Should take 1 or 2 tablets dissolved in water every 4-6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children 16-18 years:

One to two tablets every 6 hours when necessary to a maximum of 8 tablets in 24 hours

Children 12-15 years:

Children aged 12 years and above should take 1 tablet dissolved in water every 6 hours when necessary. Do not take more than 4 tablets in 24 hours.

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.

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.

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. 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.

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.**

The following effects have been reported:

- Mood changes
- Severe stomach pains (pancreatitis)
- Stomach pains
- Deafness

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- Problems with the blood (thrombocytopenia and agranulocytosis). This is usually shown by tiredness, weakness, or unexplained bruising or bleeding. This side effect is very rare.
- Skin rashes
- Constipation
- Nausea, vomiting
- Light-headedness, dizziness
- Confusion
- Drowsiness
- Urinary retention
- Rarely pancreatitis (inflammation of the pancreas which may cause severe abdominal pain that can spread through to your back)

There has been very rare reports of blood problems, so if you notice unusual bleeding or you bruise easily, tell your doctor as soon as possible.

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 all medicines 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. FURTHER 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 100 tablets.

Marketing Authorisation Holder:

Fannin (UK) Limited, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

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.

Fannin Limited, South County Business Park, Leopardstown, Dublin 18, Ireland.

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Customer: Fannin PL 20417/0029
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