

CO-CODAMOL 8/500 TABLETS

Codeine Phosphate and Paracetamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again. If you have further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. 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.

What is in this leaflet:

1. What co-codamol is and what it is used for
2. What you need to know before you take co-codamol
3. How to take co-codamol
4. Possible side effects
5. How to store co-codamol
6. Contents of the pack and other information

1. WHAT CO-CODAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-codamol 8/500 Tablets (called co-codamol throughout this leaflet). Co-codamol contains two different medicines called codeine phosphate and paracetamol. 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 painkillers such as paracetamol. Co-codamol is used to treat headache including migraine, toothache, neuralgia, period pain, pain caused by rheumatism and arthritis and to relieve the symptoms of colds, flu and sore throats. Co-codamol 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

Important things you should know about co-codamol

- Do not take for longer than your doctor tells you to
- 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
- Taking a painkiller for headaches too often or for too long can make them worse

Warnings and precautions

Do not take co-codamol and tell your doctor if:

- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients in your medicine (listed in Section 6: Further information)
- Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- The person going to take the tablets is under 12 years of age. Co-codamol must not be given to children under 12 years of age
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
- You know you metabolise very rapidly codeine into morphine
- You are breastfeeding or planning to breastfeed

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.

Take special care and check with your doctor before taking co-codamol if:

- You have severe kidney or liver problems
- You are taking a benzodiazepine

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 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 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, since the symptoms of morphine toxicity may be worse in these children.

Co-codamol is not recommended in adolescents over 12 years of age with breathing problems for the treatment of colds.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking co-codamol.

Other medicines and co-codamol

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because co-codamol can affect the way some other medicines work. Also, some other medicines can affect the way co-codamol works. Concomitant use of co-codamol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe co-codamol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

While taking co-codamol you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Tell your doctor if you are taking any of the following medicines:

- Benzodiazepines - used for treating anxiety
- Medicines used to thin the blood such as warfarin
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels

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

Pregnancy and breast-feeding

Talk to your doctor before taking these tablets if:

- You are pregnant, think you may be pregnant or plan to get pregnant.
- You are planning to breastfeed
- Do not take co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Co-codamol can affect your ability to drive as it may make you 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 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 whilst taking this medicine.

Changing or stopping treatment

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.

3. HOW TO TAKE CO-CODAMOL

Always take co-codamol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to
- Swallow the tablets whole with a drink of water

Adults: 2 tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Use in children aged 16 to 18 years: 1-2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Use in children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of 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.

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

If you take more co-codamol than you should

- 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.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken

If you have forgotten to take co-codamol

If you forget to take a dose at the right time, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking co-codamol and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to co-codamol
- You get serious skin reactions. Very rare cases have been reported.

Talk to your doctor straight away if you notice any of the following serious side effects:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect

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

- Constipation, feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem.

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

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store your medicine in the original packaging in order to protect from moisture. Do not store above 25°C. Do not throw away 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 8/500 Tablets contain

- The active substances are codeine phosphate and paracetamol. Each tablet contains 8mg of codeine phosphate and 500mg of paracetamol.
- The other ingredients are maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, talc, pregelatinised starch and purified water.

What Co-codamol 8/500 Tablets look like and contents of the pack

Flat white tablets, marked S/4 on one side. They come in cartons of 50 and 100 tablets.

The Marketing Authorisation Holder and Manufacturer is Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

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