

PACKAGE LEAFLET – INFORMATION FOR THE USER

CO-CODAMOL 8/500 EFFERVESCENT TABLETS

Codeine Phosphate and Paracetamol

- Important things you should know about co-codamol
This medicine can only be used for the short term treatment of acute moderate pain when other painkillers have not worked
You should only take this product for a maximum of 3 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 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

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 any further questions, ask your doctor or pharmacist.
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 Effervescent Tablets (called co-codamol throughout this leaflet). Co-codamol contains 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 pain killers such as paracetamol. Co-codamol is for the short term treatment of acute moderate pain caused by headaches, migraine, toothache, neuralgia, period pain and rheumatic pains when other painkillers have not worked. Wait at least 4 hours after you last took other painkillers before taking this medicine. 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

- 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
This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.
If you take a painkiller for headaches for more than 3 days it can make them worse

Warnings and precautions

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

- You are allergic to the active substances or any of the other ingredients in your medicine (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.
Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine (see "Other medicines and co-codamol").
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 that 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 have a liver problem caused by alcohol
You have problems passing water or prostate problems
You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel
You have a condition called myasthenia gravis which weakens the muscles
You suffer from hypothyroidism

- You have a disease of the adrenal gland called Addison's disease
You are taking a benzodiazepine
You are elderly
You suffer from seizures

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

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

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 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.

Other medicines and co-codamol

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 and other medicines can affect the way each other work.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking or have taken within the last two weeks:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression
medicines which make you drowsy or sleepy (CNS depressants and benzodiazepines) such as medicines used to treat anxiety or anaesthetics.
medicines for depression such as dosulepin, mirtazapine (tricyclic) or chlorpromazine (phenothiazines)
medicines known as tranquilisers, or hypnotics
sleeping tablets, sedatives and some antihistamines

You may experience more drowsiness if you take these medicines with co-codamol.

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.

Please inform your doctor or pharmacist if you are taking:

- 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.

Tell your doctor or pharmacist if you are taking any other medicines:

- Medicines used to thin the blood such as warfarin.
Chloramphenicol - an antibiotic used for infections.
Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
Colestyramine - for lowering blood cholesterol levels.
The oral contraceptive pill.

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

Co-codamol with alcohol

You should not drink alcohol while you are taking these tablets. This is because co-codamol can change the way alcohol affects you.

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.

Co-codamol contains sodium and sorbitol

- **Sodium:** This medicine contains 388 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 19.4% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sorbitol:** This medicine contains 50 mg sorbitol in each effervescent tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. HOW TO TAKE CO-CODAMOL

Always take co-codamol exactly as instructed on this leaflet. Check with your doctor or pharmacist if you are not sure.

- **Do not take more than the recommended dose.**
- **Dissolve the effervescent tablets in a glass of water before taking**

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

Children aged 16 to 18 years: 1 to 2 tablets every 6 hours when necessary up to a maximum of four doses in 24 hours.

Children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of four doses 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 under 12 years: 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 forget 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.

If you stop taking co-codamol

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

The following side effects may happen with this medicine:

Important side-effects you should know about co-codamol

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

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.
- You have a fit (seizure).
- You have difficulty breathing and you feel dizzy.

Talk to your doctor straight away if you notice the following serious side effect:

- 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), dry mouth
- Dizziness, light-headedness, drowsiness, confusion
- Feeling overly happy (euphoria)
- A feeling of unease or dissatisfaction
- Excessive constriction (shrinking) of the pupil of your eye
- Difficulty in passing water
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)
- Becoming addicted to codeine.

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.

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

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 shown 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 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 8/500 Effervescent 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 sorbitol, saccharin sodium, sodium lauryl sulphate, citric acid, sodium carbonate, sodium bicarbonate, povidone, and dimeticone.

Contents of pack

Co-codamol 8/500 Effervescent Tablets come in cartons of 24 and 32 tablets. Not all pack sizes may be marketed.

The Marketing Authorisation Holder is Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

The Manufacturer is A. Nattermann & Cie. GmbH, Nattermannallee 1, 50829 Cologne, Germany

This leaflet was last updated in October 2023