

### 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 tablet. This is equivalent to 19% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sorbitol:** This medicine contains 50 mg sorbitol in each 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 to 6 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

## 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.

### 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.
- 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 applies 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 are taking a benzodiazepine
- 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 can affect the way some other medicines work.

**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 or pharmacist if you are taking any of the following medicines, or have taken them in the past two weeks:**

- Medicines which make you drowsy or sleepy (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.
- Anti-depressant medicines such as imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine.

**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 applies 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.

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 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), 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](http://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 2020