

PACKAGE LEAFLET – INFORMATION FOR THE USER

CO-CODAMOL 15/500 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 any 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 15/500 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 moderate pain.

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**

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
- You have severe asthma attacks or severe breathing problems
- You have recently had a head injury
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred eyesight
- You have recently had an operation on your liver, gallbladder or bile duct (biliary tract)
- You are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypamine (see ‘Other medicines and co-codamol’)

- You consume excessive amounts of alcohol on a regular basis
- You are pregnant or breast-feeding
- 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.

Warnings and precautions

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

- You have severe kidney or liver problems
- 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 disease of the adrenal gland called Addison's disease
- You have a condition called myasthenia gravis which weakens the muscles
- You are elderly

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.

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

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.

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.

Do not take this medicine and tell your doctor or pharmacist if you are taking the following:

- 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, tranylcypamine

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

- Medicines which make you drowsy or sleepy (CNS depressants)

- 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 taking 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 breast-feed
- Do not take co-codamol while you are breastfeeding. Codeine and morphine passes into breast milk

Driving and using machines

You may feel dizzy or sleepy while taking co-codamol. If this happens, do not drive or use any tools or machines.

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**

Adults and children over 15 years:

- Swallow the tablets whole with a drink of water
- The usual dose of co-codamol is 2 whole tablets, taken together
- Adults should wait at least 4 hours before taking another dose
- Do not take more than 8 tablets in any 24-hour period
- Elderly people may be prescribed a lower dose

Use in children and adolescents

Children aged 12 – 15 years:

- 1 whole tablet every 4 hours
- Do not take more than 4 tablets in any 24-hour period.
- Children aged 12 years and over should wait at least 6 hours before taking another dose

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.

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.

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.

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 taking 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

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)
- 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. 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 shown on the pack. The expiry date refers to the last day of that month.

Store your medicine in the original packaging.

Do not store above 25°C.

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 15/500 Tablets contain

- The active substances are codeine phosphate and paracetamol. Each tablet contains 15mg 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 15/500 Tablets look like and contents of the pack

- White to off-white capsule-shaped tablets, marked PRO 15 and scored on one side with a plain reverse. They come in cartons of 100 tablets.

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

The Manufacturer is Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK.

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