

# Co-Dydramol Tablets 10/500mg

## Dihydrocodeine Tartrate 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.

- an **enlarged prostate** gland and have **difficulty urinating** and are **male**
- **epilepsy** or suffered **head injury** or **raised pressure** in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- an **underactive thyroid** gland
- muscle weakness (**myasthenia gravis**)
- **low blood pressure** or are in **shock**
- suffered from **alcoholism, drug abuse** or **dependence** or **mental illness**.

### Other important warnings:

- **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.**
- **Do not take for longer than directed by your prescriber.**
- **Taking dihydrocodeine 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.**

### Other medicines and Co-Dydramol Tablets

**Tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- ciprofloxacin (antibacterial medicine)
- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide) or have taken these within the last 2 weeks.
- oral contraceptives (the "pill")
- medicines to prevent blood clotting such as warfarin
- cyclizine, metoclopramide or domperidone (to prevent sickness)
- guanethidine or diuretics ("water tablets") e.g. spironolactone, furosemide (to treat high blood pressure)
- mexiletine (to treat irregular heartbeats)
- loperamide or kaolin (to treat diarrhoea)
- selegiline (for Parkinson's disease)
- phenytoin (to treat epilepsy)
- cimetidine (to treat stomach ulcers)
- atropine or hyoscine (anticholinergic medicines)
- cisapride (to treat gastro-oesophageal reflux disease)
- ritonavir (antiviral medicine)
- medicines which affect the nervous system such as sleeping tablets, diazepam, hydroxyzine and medicines to treat mental illness
- medicines to treat depression (e.g. tranylcypromine, amitriptyline)
- medicines which affect the liver (e.g. primidone and rifampicin)
- colestyramine (to treat high cholesterol levels)
- muscle relaxants
- barbiturates (e.g. phenobarbital)
- anaesthetics
- opioid antagonists (buprenorphine, naltrexone, naloxone)

### Co-Dydramol Tablets with food, drink and alcohol

If your diet is poor or you have a low protein intake, you may be at a higher risk of serious paracetamol poisoning when taking Co-Dydramol Tablets.

**Do not** drink alcohol while taking Co-Dydramol Tablets.

Swallow the tablets with **water, during or after meals**.

## What is in this leaflet

- 1 What Co-Dydramol Tablets are and what they are used for**
- 2 What you need to know before you take Co-Dydramol Tablets**
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### 1 What Co-Dydramol Tablets are and what they are used for

Co-Dydramol Tablets belong to a group of medicines called analgesics and are used for the relief of mild to moderate pain.

### 2 What you need to know before you take Co-Dydramol Tablets

**Do not take** Co-Dydramol Tablets and **tell your doctor** if you:

- are **allergic** (hypersensitive) to paracetamol, dihydrocodeine or other opioids, or any of the ingredients in the tablet (listed in section 6)
- have **diarrhoea** caused by poisoning or **severe bloody diarrhoea** (pseudomembranous colitis)
- have **difficulty breathing**, or other chronic lung disease
- are having an **asthma attack**.

### Warnings and precautions

**Talk to your doctor or pharmacist** before taking Co-Dydramol Tablets if you have:

- **liver** or **kidney** problems
- diseased adrenal glands (**Addison's disease**) or high blood pressure caused by a tumour near a kidney (**phaeochromocytoma**)
- **inflammatory bowel** disease
- **gall bladder disease** or **gall stones**
- recently had **surgery** on your gastro-intestinal tract or urinary system

## Pregnancy and breast-feeding

**Do not** take Co-Dydramol Tablets if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, unless advised by your doctor.

Regular use during pregnancy may cause withdrawal symptoms in newborn babies.

## Driving and using machines

Co-Dydramol Tablets may cause dizziness, blurred vision or the inability to think clearly. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while 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 while taking this medicine.

## 3 How to take Co-Dydramol Tablets

Always take Co-Dydramol Tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

**Do not** drink alcohol whilst taking Co-Dydramol Tablets.

Swallow the tablets with **water, during or after meals.**

Co-Dydramol Tablets are normally used only for short-term relief of symptoms, take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

### Doses:

**Adults:** 1 to 2 tablets every 4 hours up to a maximum of 8 tablets in a day.

**Elderly:** Dosage is usually reduced in the elderly.

### Use in children and adolescents:

- **Children 16-18 years:** 1 to 2 tablets every 4 hours up to a maximum of 8 tablets in 24 hours.
- **Children 12-15 years:** 1 tablet every 4-6 hours when necessary up to a maximum of 4 tablets in 24 hours.
- **Children under 12 years:** Not recommended.

**If you take more Co-Dydramol Tablets than you should**  
**Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.**

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, loss of appetite, stomach pain or liver damage, coma, clammy skin, fits, confusion, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow heart beat or breathing rate.

### If you forget to take Co-Dydramol Tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at least 4 hours later.

### If you stop taking Co-Dydramol Tablets

If you stop taking the tablets you may develop the following withdrawal symptoms tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure.

## 4 Possible side effects

Like all medicines, Co-Dydramol Tablets can cause side effects, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

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**Contact your doctor at once** if the following side effects occur:

- **Allergic Reactions** - skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face, mucosal lesions (such as mouth ulcers), drug fever
- **Abdominal pain** - may be caused by spasm of the bile ducts and inflammation of the liver or pancreas

**Tell your doctor** if you notice any of the following side effects or notice any other effects not listed:

- **Gastro-intestinal system** - stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, feeling or being sick, loss of appetite, dry mouth, difficulty in the passage of food through guts.
- **Heart** - slow heart rate, palpitations, low blood pressure especially on standing, inflammation of the heart muscle
- **Blood** - anaemia, changes in numbers and types of blood cells. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor
- **Urinary system** - pain and difficulty in passing urine and a less frequent need to do so, kidney problems.
- **Nervous system** - confusion, drowsiness, dizziness, 'spinning' sensation, mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, difficulty sleeping, nightmares, reduced alertness. Tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)
- **Eyes** - blurred or double vision, extremely small pupils
- **Others** - trembling, unusual tiredness or weakness, malaise, low body temperature, breathing difficulties, muscle stiffness. Very rare cases of skin reactions have been reported.

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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).

By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Co-Dydramol Tablets

Keep out of the sight and reach of children.

Store below 25°C in a dry place, protected from light.

Do not use Co-Dydramol Tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

## 6 Contents of the pack and other information

### What Co-Dydramol Tablets contain

- The active substances (the ingredients that make the tablets work) are 10mg of dihydrocodeine tartrate and 500mg paracetamol.
- The other ingredients are pregelatinised maize starch, maize starch, colloidal silicon dioxide, stearic acid and water.

### What Co-Dydramol Tablets look like and contents of the pack

Co-Dydramol Tablets are white, uncoated tablets.

Pack sizes are 30, 100, 500 and 1,000. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

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