



## Co-dydramol Tablets 10/500mg

(Dihydrocodeine tartrate and paracetamol)

Read all of this leaflet carefully before you start using 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### 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 use Co-dydramol Tablets
3. How to use Co-dydramol Tablets
4. Possible side effects
5. How to store Co-dydramol Tablets
6. Contents of the pack and other information

### 1. WHAT CO-DYDRAMOL TABLETS ARE AND WHAT THEY ARE USED FOR

Co-dydramol Tablets contain the active ingredients dihydrocodeine tartrate 10mg and paracetamol 500mg. Both of these are effective painkillers (analgesics) and are used for pain relief and to suppress a cough.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE CO-DYDRAMOL TABLETS

You should not be given Co-dydramol Tablets if you:

- Are hypersensitive to paracetamol, dihydrocodeine or other opioids, or any of the ingredients in the product
- Have any allergies
- Have breathing difficulties
- Suffer with chronic bronchitis or emphysema
- Suffer with asthma
- Have liver disease
- Have diarrhoea caused by poisoning or severe bloody diarrhoea (pseudomembranous colitis)
- Are having an asthma attack.

### Warnings and precautions

Check with your doctor or pharmacist before taking this medicine if you have:

- Liver problems
- Kidney disease
- 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
- 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**.

You should not take other medicines containing paracetamol at the same time as Co-dydramol Tablets (see section on Other medicines and Co-dydramol).

Do not take Co-dydramol Tablets for longer than directed by your doctor. Taking dihydrocodeine regularly for a long time can lead to addiction, which may cause you to feel restless and irritable when you stop taking the tablets. Taking painkillers for headaches too often or for too long can make them worse.

### Other medicines and Co-dydramol Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

In particular:

- Other products containing paracetamol
- 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)
- Imatinib (used to treat certain types of cancer).

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 you are taking these tablets.

### Pregnancy and breast-feeding

Do not take Co-dydramol Tablets during pregnancy or while breast-feeding unless advised by your doctor. Regular use during pregnancy may cause withdrawal symptoms in the newborn.

### Driving and using machines

These tablets may cause you to feel dizziness, blurred vision or the inability to think clearly. If you are affected you should not drive or operate machinery until you feel better.

### 3. HOW TO USE CO-DYDRAMOL TABLETS

Always take Co-dydramol Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Co-dydramol Tablets should be swallowed with a glass of water with or after a meal.

#### For pain relief:

**Adults, the elderly and children over 12 years of age:**

One tablet every 4 hours.

If necessary, your doctor may tell you to take two tablets, 4 times a day.

If you are elderly, you may be prescribed a lower dose.

#### Children under 12 years of age:

These tablets should not be taken by children under 12 years of age.

#### For coughing:

**Adults, the elderly and children over 12 years of age:**

One tablet every 4 hours.

If you are elderly, you may be prescribed a lower dose.

#### Children under 12 years of age:

These tablets should not be taken by children under 12 years of age.

#### If you take more Co-dydramol Tablets 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.

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

If you have forgotten to take a dose, take the dose as soon as you remember if needed for relief of symptoms. If not needed, do not take the missed dose, simply take your next dose at the scheduled time.

#### If you stop taking Co-dydramol Tablets

Do not stop taking Co-dydramol Tablets without consulting your doctor as your condition may deteriorate.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-dydramol Tablets can cause side effects, although not everyone gets them.

**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
- Very rare cases of serious skin reactions have been reported
- **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:

- **Gastrointestinal 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.

### 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

Check the expiry date printed on the label or side of the box. Do not use after the expiry date stated on the label.

Do not store above 25°C. Store in the original package to protect from light.

In case of any visible signs of deterioration, you should discard the package.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

### Keep out of the sight and reach of children

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Co-dydramol Tablets contain

Co-dydramol Tablets contain 10mg dihydrocodeine tartrate and 500mg paracetamol per tablet.

The other ingredients are: maize starch, povidone, stearic acid, sodium starch glycollate, colloidal silicon dioxide and talc.

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

Co-dydramol Tablets are white, round, biconvex tablets with 15 marked on one side and L on the reverse side.

Co-dydramol Tablets are available in packs of 25, 50, 100, 250, 500 and 1,000 tablets.

#### Marketing Authorisation Holder

Ennogen Pharma Limited,  
Unit G4, Riverside Industrial Estate,  
Riverside Way, Dartford, DA1 5BS. UK.

#### Manufacturer

CLONMEL CHEMICALS LTD  
Clonmel, Ireland

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