

Package leaflet: Information for the user
Co-dydramol 10/500mg Tablets
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.

The name of your medicine is Co-dydramol 10/500mg Tablets. In the rest of this leaflet, it is called Co-dydramol Tablets.



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
3. How to take 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

The active ingredients in Co-dydramol Tablets are paracetamol and dihydrocodeine tartrate. They belong to a group of medicines called analgesics, which act as painkillers. These tablets are usually used for the treatment of mild to moderate pain in muscles and joints (e.g. arthritic pain, sprains, strains etc.).

2. What you need to know before you take Co-dydramol Tablets

Do not take Co-dydramol Tablets if you:

- are allergic to paracetamol, dihydrocodeine tartrate, or any of the other ingredients of this medicine (listed in section 6).
- drink excessive amounts of alcohol.
- have severe asthma, bronchitis, breathing problems or if you are having an asthma attack.
- have recently had a head injury or have increased pressure within your head (raised intracranial pressure).
- are under 12 years of age.
- have an inflamed bowel or obstructive bowel disorder.
- have severe diarrhoea.
- are in a coma.
- have been told you have liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-dydramol Tablets.

This product contains paracetamol.

- Do not take with any other paracetamol containing products.
- If your symptoms last for more than 3 days talk to your doctor.
- Do not take for longer than directed by your prescriber.
- Taking dihydrocodeine (DHC) 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.

Talk to your doctor or pharmacist before taking Co-dydramol Tablets if you:

- are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below).
- are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression.
- have asthma.
- have serious problems with your liver or kidneys.
- are elderly, as you may need a lower dose.
- are being treated with depressants (medicines used to treat anxiety).
- have an under active thyroid.
- have Addison's disease.
- have inflammation of the bowel or a blockage of the bowel.
- suffer from myasthenia gravis (a disease characterised by weakness of certain groups of muscles).
- suffer from biliary tract disorders such as gallstones.
- are a poor metaboliser of codeine.

- have low blood pressure (hypotension).
- have an enlarged prostate.
- have had a drug addiction.
- have had shock.

Caution should be exercised when taking paracetamol prior to (less than 72 hours before) or at the same time as intravenous busulfan.

Other medicines and Co-dydramol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect or be affected by Co-dydramol Tablets:

- Anticonvulsants (to treat epilepsy).
- Antidepressants (tricyclics or MAOIs).
- Anxiolytics such as diazepam (to help with anxiety).
- Antipsychotics (to help mood disorders).
- Hypnotics (to help you sleep).
- Chloramphenicol (an antibiotic).
- Colestyratime (used to lower cholesterol).
- Cisapride, metoclopramide or domperidone (used to stop you feeling sick or being sick).
- Anticoagulants (medicines used to thin the blood, such as warfarin and acenocoumarol).
- Anti-HIV agents such as zidovudine and ritonavir.
- Anaesthetics, particularly general anaesthetics (used in surgery to numb pain).
- Antihistamines such as benadryl (used to treat allergies e.g. hayfever).
- Sodium oxybate (used to treat narcolepsy).
- Anti-arrhythmics such as mexiletine and quinidine.
- Anti-diarrhoeal and antiperistaltic agents (such as loperamide and kaolin).
- Cimetidine (used to treat stomach ulcers and indigestion).
- Oral contraceptives.
- Anti-bacterial agents such as isoniazid.
- Gout suppressants such as probenecid.
- Non-steroidal anti-inflammatory drugs (NSAIDs).
- intravenous busulfan (used in chemotherapy to treat cancer).

Co-dydramol Tablets with food, drink and alcohol

These tablets should be swallowed with a glass of water, with or immediately after food.

Do not drink alcohol while you are taking Co-dydramol Tablets. Alcohol may increase the sedative effects of co-dydramol and make you very sleepy.

It can also increase the risk of some side effects.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Codeine may cause drowsiness and blurred or double vision in some people. Do not drive or use any tools or machines if you are affected in this way and do not drink alcohol, as this will make these effects worse. Other medicines may also increase these effects.

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 this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure. The recommended dose is described below.

These tablets are for oral administration.

Dosage instructions

Adults and children 16 years and over: One to two tablets every four to six hours. Do **not** take

more than eight tablets in 24 hours.

Children 12-15 years: One tablet every four to six hours when necessary to a maximum of four doses in 24 hours.

Elderly: Your doctor may have reduced the dose for you. If this is the case follow your doctor's instructions.

You may need a reduced dose if you have liver, kidney or thyroid problems.

Children under 12 years: Do not give to children under 12 years. Do not take more tablets than your doctor has prescribed for you.

If you take more Co-dydramol Tablets than you should

Always take the medicine as recommended by your doctor. 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

Take your usual dose as soon as you remember, provided it is at least 4 hours since your last dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-dydramol Tablets

Do not stop taking these tablets immediately, it could make you feel restless or irritable. Talk to your doctor about reducing your dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you think your medicine is making you feel unwell.

It is very unlikely that you will experience the following side effects. However, you should **stop** taking this medicine and talk to your doctor **immediately** if you notice any of the following symptoms:

- You have a severe abdominal pain (in the upper middle or upper left part of the belly) usually accompanied by sickness, diarrhoea or fever.
- You have an allergic reaction. The signs of an allergic reaction may include: a rash, itching, difficulty breathing or swallowing, swelling of your lips, face, throat or tongue.
- You have low blood pressure.

Other more common side effects that some people notice when taking Co-dydramol are listed below:

- Constipation
- Nausea (feeling sick)
- Drowsiness and
- Vomiting (being sick)

Rare side effects on long-term use include:

- Kidney damage
- Blood cell changes.
- Inflammation of the pancreas.
- Difficulty or pain on urination.
- Dry mouth.
- Confusion.
- Sweating and facial flushing.
- Palpitations (awareness of your heart beat).
- Difficulty breathing.
- Stomach cramps.
- Increased or decreased frequency of passing urine.
- Vertigo (a feeling of dizziness or 'spinning').
- Low blood pressure.

- Blurred or double vision.
- Loss of balance or dizziness on standing.
- Hypothermia (suddenly feeling very cold).
- Slowing of or increased awareness of heart beat.
- Hallucinations (seeing or hearing things that are not there).
- Nightmares.
- Mood changes such as depression and sadness.
- Narrowing of the pupils.
- Headache.
- Feeling of well being (known as euphoria).
- Muscle rigidity or weakness.
- Increased pressure within your head (raised intracranial pressure).
- (abnormally high levels of glucose in the blood).
- Feeling unwell.
- Feeling tired.
- Fever.
- An enlarged spleen or swollen/enlarged lymph nodes.
- Anorexia.
- Biliary spasms (causing a pain in the right side of your abdomen, particularly after eating a meal).
- Weak erection in men.
- Uncontrolled muscle movements.
- Low sex drive
- Restlessness.

Very rarely may cause fits in children.

Overdosage may give rise to liver damage, coma and death.

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-dydramol Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister or if they show signs of deterioration. The expiry date refers to the last day of that month.

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

Remember, this medicine is for **you only**. **Never** give it to anyone else. It may harm them, even if their symptoms are the same as yours. Unless your doctor tells you to, do not keep tablets that you no longer need. Give them back to the pharmacist.

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-dydramol Tablets contains

The active ingredients in Co-dydramol Tablets are paracetamol, 500mg and dihydrocodeine tartrate, 10mg.

The other ingredients are pregelatinised starch, povidone K30, magnesium stearate and water.

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

Co-dydramol Tablets are white flat bevelled edge tablets marked DDM with a breakline on one face and CP on the reverse.

Co-dydramol Tablets are available in packs of 30, 100 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product Name	Reference Number
Co-dydramol 10/500mg Tablets	PL29831/0051

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