

PACKAGE LEAFLET - INFORMATION FOR THE USER

CO-DYDRAMOL 10mg/500mg TABLETS
 Dihydrocodeine Tartrate and Paracetamol

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT CO-DYDRAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-dydramol 10mg/500mg Tablets (called co-dydramol throughout this leaflet). Co-dydramol contains two different medicines called paracetamol and dihydrocodeine tartrate. It belongs to a group of medicines called analgesics (painkillers) and is used to treat mild to moderate pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-DYDRAMOL
Important things you should know about co-dydramol

- Do not take for longer than your doctor tells you to.
- Taking co-dydramol 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-dydramol 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 breathing problems
- You are having an asthma attack
- You have liver disease
- You are an alcoholic

Do not take co-dydramol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking co-dydramol.

Children

Co-dydramol must not be given to children under 12 years of age.

Warnings and precautions
Take special care and check with your doctor before taking co-dydramol if:

- You have kidney problems
- You have asthma
- You have problems with your thyroid gland (hypothyroidism)
- You are in the last three months of pregnancy (see Pregnancy and breast-feeding section)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and co-dydramol

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-dydramol and some other medicines can affect the way each other work.

While taking co-dydramol 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 if you are taking any of the following medicines:

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) such as moclobemide, phenelzine, tranylcypromine or have taken them in the last 2 weeks.
- Medicines which make you drowsy or sleepy
- Medicines used to thin the blood such as warfarin
- Metoclopramide or domperidone - used to stop you feeling or being sick (nausea or vomiting)
- Colestyramine - for lowering blood cholesterol levels

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking co-dydramol.

Co-dydramol with alcohol

You should not drink alcohol while you are taking these tablets.

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 breast-feeding or planning to breast-feed

Driving and using machines

Co-dydramol 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.

Changing or stopping treatment

Taking co-dydramol for a long time may lead to tolerance and dependence. Do not increase or suddenly stop treatment without discussing this with your doctor.

3. HOW TO TAKE CO-DYDRAMOL

Always take co-dydramol 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
- Swallow the tablets whole with a glass of water

Adults and children over 16 years: 1 to 2 tablets every 4 to 6 hours when necessary up to a maximum of eight tablets in 24 hours. Elderly people may be prescribed a lower dose.

Use in children aged 12 to 15 years: 1 tablet every 4 to 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Co-dydramol should not be given to children under 12 years of age.

If you take more co-dydramol 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-dydramol

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-dydramol

- Taking a painkiller for headaches too often or for too long can make them worse.
- Taking co-dydramol 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-dydramol 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-dydramol.
- You get serious skin reactions. Very rare cases have been reported.

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)
- Headache, dizziness, light-headedness, drowsiness, confusion
- Becoming dependent on dihydrocodeine
- You get infections or bruise more easily than usual. This could be because of a blood problem.
- Redness or blood spots on the skin (purpura)

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

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 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 contain

- The active substances are 500mg of paracetamol and 10mg of dihydrocodeine tartrate. The other ingredients are pregelatinised starch, maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, purified talc and magnesium stearate.

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

Flat bevelled edge white tablets, marked S/8 on one side. They come in cartons of 30 and 100 tablets.

The Marketing Authorisation Holder and Manufacturer is Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK. This leaflet was updated in January 2017



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Co-dydramol TABS
-30's & 100's pack
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