

Co-Dydramol 10/500mg Tablets

(Dihydrocodeine Tartrate and Paracetamol)

This medicine contains Dihydrocodeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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, please 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.

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

The name of your medicine is Co-dydramol 10/500mg Tablets (called co-dydramol throughout this leaflet). This medicine has been prescribed for you to treat mild to moderate pain and fever. It may help reduce a cough. It contains the dihydrocodeine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

Co-dydramol also contains paracetamol, another analgesic used to help relieve pain and fever.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop and how to do this safely.

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 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 of this 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 or lungs disease
- 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

Talk to your doctor before taking co-dydramol if:

- You have kidney and liver 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)
- You have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting)

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

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of co-dydramol to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak

to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

Concomitant use of co-dydramol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe co-dydramol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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 (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.
- Antidepressant medicines such as imipramine, amitriptyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine.
- 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.
- Mexiletine (used to treat irregular heartbeat).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

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

Pregnancy
Do not take co-dydramol if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. If necessary, co-dydramol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often. If you use co-dydramol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breastfeeding

Do not take dihydrocodeine while you are breastfeeding. Dihydrocodeine passes into breast milk and will affect your baby.

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.

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. Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.
- You should take your medicine during or after meals. Swallow the tablets whole with a glass of water. Do not chew the tablets.

Adults and children over 16 years

For pain relief:

1 to 2 tablets every 4 to 6 hours when necessary up to a maximum of eight tablets in 24 hours.

For cough relief:

1 tablet every 4 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. 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 heartbeat or breathing rate.
- 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.

If you stop taking co-dydramol

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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. 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.

- if 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.
- You get infections or bruise more easily than usual. This could be because of a blood problem.

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

Not known (frequency cannot be estimated from the available data):

- Dependence and addiction (see section "How do I know if I am addicted?")
- Abdominal pain
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Drug Withdrawal

When you stop taking co-dydramol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking co-dydramol, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5 HOW TO STORE CO-DYDRAMOL

- Do not store above 25°C. Store in the original container.
- 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.
- 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 to 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 povidone, stearic acid, croscarmellose sodium, talc, sodium starch glycollate (Type A), and silica colloidal anhydrous.

What co-dydramol Tablets looks like and the contents of the pack:

White, circular, flat, bevel edged tablets with a horizontal line and logo "T2" engraved on one side and plain on the other side.

Co-dydramol Tablets are available in:

Co-dydramol are available in packs of 25, 30, 50, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

JCSH Pharma Limited
Winslade, Shere Road, West Clandon
Surrey, GU4 8SF United Kingdom

Manufacturer:

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