PATIENT INFORMATION LEAFLET

CO-DYDRAMOL 20/500 MG TABLETS & 30/500 MG TABLETS

(dihydrocodeine tartrate & paracetamol)

9528C

Read all of this leaflet carefully before you start taking this medicine.
This medicine contains dihydrocodeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- 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. Do not pass it on to others, it may harm them, even if their symptoms 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.

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 contain paracetamol and dihydrocodeine which are analgesics (painkillers). Co-dydramol Tablets are used to relieve severe pain. Dihydrocodeine 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. 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, how to do this safely.

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

Do NOT take this medicine if you:
- are allergic (hypersensitive) to paracetamol, dihydrocodeine or any of the other ingredients of this medicine (listed in section 6)
- are having an asthma attack
- have other breathing problems or lung disease which makes breathing difficult.

DO NOT TAKE WITH ANY OTHER PARACETAMOL OR CODEINE CONTAINING PRODUCTS.

Warnings and precautions
- Do not take for longer than directed by your doctor.
- Taking dihydrocodeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablet.
- Taking a painkiller for headaches too often or for too long can make them worse.

Tell your doctor before you start this medicine if you:
- suffer from asthma or allergies
- have kidney disease or problems with kidney function
- have long term liver disease
- have increased pressure in the brain, e.g. following a brain or head injury
- have prostate or urinary problems e.g. difficulty passing water
- are an alcoholic
- have an underactive thyroid gland (hypothyroidism)
- are elderly

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 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 Tablets
Talk to your doctor or pharmacist before you take this medicine if you are taking any of the following:
- medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 14 days. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine
- medicines which make you drowsy or sleepy (CNS depressants) such as antidepressants, sleeping tablets, tranquilisers or medicines for psychiatric or mental disorders
- medicines to prevent blood clotting, such as warfarin
- colestyramine (used to reduce cholesterol in the blood)
- metoclopramide or domperidone (used to treat nausea and vomiting)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used

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

Co-dydramol Tablets with alcohol
You should not drink alcohol while you are taking these tablets. This is because Co-dydramol Tablets can change the way alcohol affects you.

Pregnancy and breastfeeding
- Do not take Co-dydramol Tablets 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 you use Co-dydramol Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
- Do not take Co-dydramol Tablets while you are breastfeeding as dihydrocodeine passes into breast milk and will affect your baby.

Driving and using machines
If these tablets make you feel drowsy, do not drive or operate machinery. Co-dydramol Tablets 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

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.
Two different strengths of tablets are available. Your doctor will decide which strength of tablet will suit you best.
Always take this medicine exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.

- Swallow the tablets with a glass of water, preferably during or after a meal.
- Do not take more medicine than the label tells you to.

Children under 12 years:
Not recommended

12-15 years age group:
1 tablet every four to six hours. Do not exceed four tablets in any 24 hour period.

Adults, aged 16 and over:
Take one or two tablets every four to six hours. Do not take more than 2 tablets at once and do not take more than 8 tablets in 24 hours

Elderly:
One tablet every 4-6 hours increasing to two tablets every 4-6 hours if required and tolerated. Do not exceed eight tablets in any 24-hour period.
Caution should be taken when increasing the dose in the elderly.
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 the doctor is not there, go to your local hospital casualty department. Take this leaflet and any remaining tablets with you.
The hazard of overdose with paracetamol is greater in those with alcoholic liver disease.

If you forget to take Co-dydramol Tablets
If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. 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 Tablets
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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-dydramol Tablets can cause side effects, although not everybody gets them.
Stop taking the tablets and tell your doctor immediately or go to the nearest hospital casualty department if you have any of the following:

- symptoms of an allergic reaction (rare side effect), such as swelling of the lips, face or neck leading to severe difficulty breathing, skin rash or hives
- you get serious skin reactions (red rash, blistering, skin peeling or swelling/ blistering of the mouth, throat or eyes).
  Very rare cases have been reported.

Tell your doctor straight away if you notice the following serious side effect:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas. This is a very rare side effect.

Tell your doctor or pharmacists if any of the following side effects gets worse or lasts longer than a few days:

- Constipation
- Abdominal pain
- Feeling sick (nausea), being sick (vomiting)
- Itching skin
- Headache
- Feeling of dizziness or spinning, light-headedness, giddiness
- Drowsiness
- Hallucinations
- Feeling in an unpleasant or uncomfortable mood
- Problems in passing urine
- You get infections more often or bruise more easily than usual. This could be because of a blood problem.
- A need to take higher doses to obtain the same level of pain relief (tolerance)
- Becoming dependent or addicted to dihydrocodeine (which can lead to restlessness and irritability when you stop taking the tablets) - see section "How do I know if I am addicted?".

Drug Withdrawal
When you stop taking Co-dydramol Tablets, 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 tablets, 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 TABLETS

Keep out of the sight and reach of children
Do not store above 25 °C. Store in the original package in order to protect from moisture.
Do not use this medicine after the expiry date printed on the pack. The expiry date refers to the last day of that month.
Do not throw away any medicines via waste water 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 ingredients in each tablet are paracetamol and dihydrocodeine tartrate.
Co-dydramol 20/500 mg Tablets contain dihydrocodeine tartrate 20 mg and paracetamol 500 mg.
Co-dydramol 30/500 mg Tablets contain dihydrocodeine tartrate 30 mg and paracetamol 500 mg.
The other ingredients are maize starch, povidone, colloidal silica, magnesium stearate and potassium sorbate (E202).

What Co-dydramol Tablets looks like and contents of the pack:
The tablets are white, capsule-shaped tablets, engraved on one side with "CODY20" or "CODY30" and plain on the reverse.
They are available in packs of 56 and 112.

Marketing Authorisation Holder
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