CO-DYDRAMOL 20/500mg & 30/500mg TABLETS
Dihydrocodeine Tartrate, Paracetamol

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

1. What Co-dydramol Tablets are and what they are used for

These tablets have been prescribed for you to relieve severe pain over a period of 4 to 6 hours. They contain the active ingredients dihydrocodeine tartrate and paracetamol which belong to a group of medicines called strong analgesics or “painkillers”.

The other ingredients are listed in section 6 of this leaflet.

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

Do not take Co-dydramol Tablets:

- if you are allergic to dihydrocodeine, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- if you have breathing problems, such as breathing more slowly or weakly than expected, or obstructive airways disease
- if you are having an asthma attack.

Children under 12 years of age should not take these tablets.

Warnings and precautions

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

- if you have asthma or any allergies
- if you have an under-active thyroid gland (hypothyroidism)
- if you have kidney or long-term liver problems
- if you have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the tablets may make these symptoms worse or hide the extent of a head injury
- if you have prostate problems
- if you are addicted to alcohol
- if you are or have ever been addicted to drugs.

Other special warnings:

- Do not take anything else containing paracetamol while taking this medicine.
- Do not take for longer than directed by your prescriber.
- Taking dihydrocodeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

3. How to take Co-dydramol Tablets

1 or 2 tablets every four to six hours when necessary. Do not take more than 4 tablets in 24 hours.

Children 12 to 15 years: 1 tablet every six hours when necessary.

4. Possible side effects

The following side effects have also been commonly reported in patients treated with these tablets:

- You may feel sick or vomit (be sick) when you take these tablets. Your doctor will prescribe a laxative to overcome this problem.
- Most people will have constipation when they take these tablets. Your doctor will prescribe a laxative to overcome this problem.
- Driving and using machines

You may feel sleepy when taking these tablets. If you are affected you should avoid driving alcohol.

5. How to store Co-dydramol Tablets

- This medicine is available in pack sizes of 2, 8, 12, 28, 56, and 100 tablets.
- Store in the original package.
- Keep tightly closed to protect the tablets from moisture.
- Do not throw away any medicines via wastewater or sewage. They may be harmful to the environment.

6. Contents of the pack and other information

Other medicines and Co-dydramol Tablets

Tell your doctor or pharmacist if you are taking:

- any other medicines containing paracetamol (you should not take these tablets if you are already taking another medicine containing paracetamol)
- medicines to help you sleep (for example: tranquilisers, hypnotics or sedatives).
- medicines to treat psychiatric or mental disorders
- a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks.
- medicines to treat depression or anxiety
- metoclopramide or domperidone to stop you feeling or being sick
- codeine to treat high blood pressure or diarrhoea
- medicines such as warfarin to prevent your blood clotting or to help thin your blood.

Co-dydramol Tablets with alcohol

Drinking alcohol during your treatment with these tablets may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breast-feeding

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

You may feel sleepy when taking these tablets. If you are affected you should not drive or use machinery. This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain - go to https://www.gov.uk/drug-driving-law.

What is in this leaflet

This leaflet contains the following sections:

- 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

What is this medicine

Dihydrocodeine Tartrate, Paracetamol - Keep this leaflet. You may need to read it again.

Printing information

This leaflet does not print. Do not reproduce it.

Note: Grey area does not print
Use in children and adolescents:
Children 16 to 18 years: 1 or 2 tablets every six hours when necessary. Do not take more than 8 tablets in 24 hours.
Children 12 to 15 years: 1 tablet every six hours when necessary. Do not take more than 4 tablets in 24 hours.
Children under 12 years should not take this medicine.
Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

If you take more Co-dydramol Tablets than you should
Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick, and have abdominal pain. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. 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. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take Co-dydramol Tablets
If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Co-dydramol Tablets
You should not stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first.
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.
All medicines can cause allergic reactions, although serious allergic reactions are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. As with all strong painkillers, there is a risk you may become addicted or reliant on these tablets.
Taking a painkiller for headaches too often or for too long can make your headaches worse.
Tell your doctor or pharmacist if you notice any of the side effects listed in the sections below:
Common: may affect up to 1 in 10 people
Most people will have constipation when they take these tablets. Your doctor will prescribe a laxative to overcome this problem.
You may feel sick or vomit (be sick) when you take your tablets, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.
You may find that you feel more sleepy than normal when you start taking your tablets or when your dose is increased. This should wear off after a few days.
The following side effects have also been commonly reported in patients treated with these tablets:
- headache
- rash or itchy skin.
Uncommon: may affect up to 1 in 100 people
- an unpleasant or uncomfortable mood
- hallucinations
- a feeling of dizziness or “spinning”
- difficulty in passing urine
- a need to take increasingly higher doses to obtain the same level of pain relief (tolerance)
- withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking the tablets.
Rare: may affect up to 1 in 1,000 people
- inflammation of the pancreas (which causes severe pain in the abdomen and back)
- abnormal cells in the blood (blood dyscrasias).
Very rare cases of serious skin reactions have been reported.

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. 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. The expiry date refers to the last day of that month.
Do not store your tablets above 30°C. Keep the bottle tightly closed to protect the tablets from moisture.
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 contain
The active ingredients are paracetamol and dihydrocodeine tartrate.
Each Co-dydramol 20/500mg tablet contains 500mg of paracetamol and 20mg of dihydrocodeine tartrate.
Each Co-dydramol 30/500mg tablet contains 500mg of paracetamol and 30mg of dihydrocodeine tartrate.
The other ingredients are magnesium stearate and maize starch.

What Co-dydramol Tablets look like and contents of the pack
Co-dydramol 20/500mg Tablets are white and marked PD/20.
Co-dydramol 30/500mg Tablets are white and marked PD/30.
This medicine is available in pack sizes of 2, 8, 12, 28, 56, 112 or 200 tablets. (Not all pack sizes may be marketed).

Marketing Authorisation Holder
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If you require this leaflet in a different format please contact the Marketing Authorisation Holder at the address above.