

Patient information Leaflet

Co-dydramol Tablets

Important information about Co-dydramol

- Do not take this medicine for longer than your doctor tells you

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 any further questions, please 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 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

In this leaflet:

1. What Co-dydramol is and what it is used for
2. What you need to know before you take Co-dydramol
3. How to take Co-dydramol
4. Possible side effects
5. How to store Co-dydramol
6. Contents of the pack and other information

1. What Co-dydramol is and what it is used for

The name of your medicine is Co-dydramol Tablets.

Co-dydramol contains two different medicines called:

- Dihydrocodeine
- Paracetamol

These medicines both belong to a group of medicines called pain-killers (analgesics) Co-dydramol is used to provide relief from pain and to also prevent or relieve coughing.

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

Do not take Co-dydramol if:

- You are allergic (hypersensitive) to dihydrocodeine, paracetamol or any of the other ingredients (listed in Section 6 below)
- You have severe asthma attacks or severe breathing problems

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.

During treatment with Co-dydramol, tell your doctor straight away if:

If 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).

Take special care with Co-dydramol

Check with your doctor or pharmacist before taking Co-dydramol if:

- You are pregnant or breast-feeding (see Pregnancy and breast-feeding section below)
- You have severe kidney or liver problems
- You have an underactive thyroid gland

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

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.

Taking other medicines

Please 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 can affect the way some other medicines work. Also some other medicines can affect the way Co-dydramol works.

While taking Co-dydramol you should not take any other medicines which contain paracetamol

This includes other pain-killers, and some cough and cold remedies. It also includes other medicines available from your pharmacist and more widely in shops. Always check the name of the medicines inside anything you buy or are prescribed, to see if they contain paracetamol.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Metoclopramide or domperidone - used for feeling sick (nausea) or being sick (vomiting)
- Cholestyramine - used for high cholesterol and fat levels in the blood
- Medicines used to thin the blood (such as warfarin)
- 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 the above apply to you, talk to your doctor or pharmacist before taking Co-dydramol.

Taking Co-dydramol with food and drink

Drinking alcohol while taking this medicine can make you feel sleepy. Alcohol should be avoided during treatment with Co-dydramol.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

Regular use of co-dydramol during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.

Driving and using machines

You may feel sleepy or dizzy after taking Co-dydramol . If this happens, do not drive or use any tools or machines.

Important information about Co-dydramol

- Do not take for longer than directed by your prescriber
- Taking codeine 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.

3. How to take Co-dydramol

Always take Co-dydramol as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Do not take more than the dose you have been told**
- **Do not take for longer than your doctor tells you**

How much to take

Adults and children over 15 years of age

- The usual dose of Co-dydramol is one tablet taken every 4 hours
- For pain relief, the dosage may be increased to two tablets every 6 hours if necessary
- Do not take more than 8 tablets in any 24 hour period
- Swallow the tablets whole, during or after food with a glass of water
- Elderly people may be given a lower dose

Children 12-15 years of age

- One tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 12 years of age

- Co-dydramol is not recommended for use in children under 12 years of age.

If you think that the effect of Co-dydramol is too strong or too weak, talk to your doctor or pharmacist.

Changing the dose after taking Co-dydramol regularly for a long time

Taking Co-dydramol regularly and for a long time can make you addicted to the medicine. If you have taken regular daily doses of Co-dydramol for a long time, talk to your doctor before increasing the dose or before suddenly stopping treatment.

If you take more Co-dydramol than you should

- If you take more Co-dydramol than you should, talk to your doctor or go to a hospital straight away. This is because there is a risk of serious liver damage, though this may not happen straight away. 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 this medicine pack and any remaining tablets with you, so the doctor knows what you have taken

If you forget to take Co-dydramol

- If you forget a dose, do not worry, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Co-dydramol can cause side effects, although not everybody gets them.

Important side effects you should know about Co-dydramol

- Taking dihydrocodeine regularly for a long time can make you addicted to the medicine. This means that when you stop taking the tablets, you might feel restless and irritable
- Taking a painkiller for headaches too often or for too long can make them worse

Stop taking Co-dydramol and see a doctor straight away if:

- You develop an allergic reaction. Signs of an allergic reaction include a rash, swelling of your face, lips, mouth and throat, difficulty swallowing or difficulty breathing

Other possible side effects may include:

- Constipation
- Feeling sick (nausea)
- Abdominal or stomach pain
- Headache
- Feeling dizzy or light-headed
- Blood problems such as thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising) and agranulocytosis (severe reduction in number of white blood cells which makes infections more likely)

- Withdrawal symptoms.

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

“A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)”

If any of the side effects get serious or lasts for longer than a few days or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Co-dydramol

Keep out of the reach and sight of children.

Do not use Co-dydramol after the expiry date stated on label. The expiry date refers to the last day of the month.

Store your medicine in a cool dry place below 25°C and protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Co-dydramol Tablets contain:

- The active ingredients are dihydrocodeine tartrate and paracetamol. Each tablet contains 10 mg of dihydrocodeine tartrate and 500 mg of paracetamol
- The other ingredients are maize starch, povidone, sodium starch glycollate, stearic acid, colloidal silicon dioxide and talc

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

Co-dydramol Tablets are white, flat, circular plain tablets with a bevel edge and breakline.

They are available as packs of 16, 25, 32, 50, 100, 250, 500 or 1000 tablets in securitainers or packs of 16, 32 or 100 tablets in PVC blisters.

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder:

Activase Pharmaceuticals Limited
11 Boumpoulinas, 3rd Floor
P.C. 1060 Nicosia,
Cyprus

Manufacturer:

TBC

Date of leaflet revision: February 2025