

Dihydrocodeine 120 mg, prolonged-release tablets
Dihydrocodeine tartrate

Package Leaflet: Information for the patient

Dihydrocodeine 60 mg, 90 mg, and 120 mg prolonged-release tablets
Dihydrocodeine tartrate

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, 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.

What is in this leaflet:

1. What ***Dihydrocodeine*** tablets are and what they are used for
2. What you need to know before you take ***Dihydrocodeine*** tablets
3. How to take ***Dihydrocodeine*** tablets
4. Possible side effects
5. How to store ***Dihydrocodeine*** tablets
6. Contents of the pack and other information

1. What *Dihydrocodeine* tablets are and what they are used for

This medicine has been prescribed for you for the relief of severe pain over a period of 12 hours. It contains dihydrocodeine, which belongs to a class of medicines called opioids, which are ‘pain relievers’. The medicine has been prescribed for 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 doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

The tablets may be taken by adults and children aged 12 years and above.

2. What you need to know before you take *Dihydrocodeine* tablets

Do not take *Dihydrocodeine* tablets if you:

- are allergic (hypersensitive) to dihydrocodeine or any of the other ingredients of the tablets (listed in section 6 of this leaflet);
- have severe breathing problems such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- are having an asthma attack;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus);
- are currently intoxicated from drinking alcohol;
- have an intolerance to some sugars;
- are under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you:

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- 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 ***Dihydrocodeine*** tablets 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 doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- are elderly;
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick, as this may indicate that the pressure in your skull is increased. This is because the tablets may make these symptoms worse or hide the extent of any head injury;
- are feeling unusually light-headed or faint;
- have breathing problems such as chronic obstructive lung disease, bronchial asthma or respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have an under-active thyroid gland (hypothyroidism);
- have severe kidney problems;
- have liver problems;
- have constipation or an obstructive bowel disorder;
- have inflammation of the pancreas (which causes severe pain in the abdomen and back);
- have problems with your gall bladder or bile duct;
- have an enlarged prostate gland, which causes difficulty in passing urine (in men).
- have a heart problem after long-term lung disease (cor pulmonale);
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using 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 doctor 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 doctor 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.

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Other medicines and *Dihydrocodeine* tablets

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

Taking ***Dihydrocodeine*** tablets at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:

- other medicines used to treat pain known as opioids (such as codeine or morphine);
- medicines used to treat anxiety;
- medicines used to make you feel sleepy (such as benzodiazepines);
- medicines used to treat psychiatric or mental disorders (such as phenothiazines);
- medicines used to treat depression;

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- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not take ***Dihydrocodeine*** tablets if you are currently taking this type of medicine or have taken this medicine in the last two weeks. Because of this, your doctor will only prescribe ***Dihydrocodeine*** tablets where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately.

***Dihydrocodeine* tablets and alcohol**

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

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking these tablets.

Pregnancy

Do not take ***Dihydrocodeine*** tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take ***Dihydrocodeine*** tablets during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated, such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea.

Breast-feeding

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

Driving and using machines

These tablets may cause a number of side effects such as drowsiness, which could affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full list of side effects). These are usually most noticeable when you first start taking the tablets or when changing to a higher dose. If you are affected you should not drive or use machinery.

- 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.

***Dihydrocodeine* tablets contain lactose**

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take *Dihydrocodeine* tablets

Always take these tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often. Do not take for longer than directed by your doctor. Check with your doctor or pharmacist if you are not sure.

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Your doctor should have discussed with you how long the course of *Dihydrocodeine* 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.

Swallow your tablets whole with a glass of water. **Do not break, chew or crush them.**

***Dihydrocodeine* tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

Adults and children over 12 years of age

The usual starting dose is 60 mg to 120 mg every 12 hours. If you are elderly your doctor may suggest a lower starting dose. Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor.

Use in children

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

If you take more *Dihydrocodeine* tablets than you should or if someone accidentally swallows your tablets

Call your doctor or hospital **immediately**. People who have taken an overdose may feel very sleepy, sick or dizzy. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. 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 *Dihydrocodeine* tablets

If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten tablet.

If you stop taking *Dihydrocodeine* tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine discuss this with your doctor 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, these tablets can cause side effects, although not everybody gets them. This medicine 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, lips or throat, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and *Dihydrocodeine* tablets'). Tell your doctor **immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

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Drug withdrawal

When you stop taking ***Dihydrocodeine*** 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 ***Dihydrocodeine*** 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 doctor.

Taking a painkiller for headaches too often or for too long can make your headaches worse.

Common side effects (May affect more than 1 in 100 people)

- constipation (your doctor can prescribe a laxative to overcome this problem);
- feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem);
- drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days);
- dry mouth, abdominal pain or discomfort.

Uncommon side effects (May affect fewer than 1 in 100 people)

- withdrawal symptoms (see section 'Drug Withdrawal');
- diarrhoea;
- a condition where the bowel does not work properly (paralytic ileus);
- mood changes, unpleasant or uncomfortable mood;
- headache, confusion, a feeling of unusual weakness, tiredness, generally feeling unwell;
- hallucinations;
- blurred vision;
- a feeling of dizziness or spinning (vertigo), seizures, fits or convulsions;
- tingling or numbness;
- low blood pressure;
- decreased sexual drive;
- difficulty or pain in passing urine;
- swelling or puffiness of the skin, flushing of the skin;
- itching, redness or rash, or a raised itchy rash (hives);
- shortness of breath;
- increased sweating;
- a need to take increasingly higher doses to obtain the same level of pain relief (tolerance);
- abdominal pain or discomfort;
- a worsening in liver function tests (seen in a blood test).

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- dependence and addiction (see section 'How do I know if I am addicted?');
- development of a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- withdrawal symptoms in babies born to mothers who have used ***Dihydrocodeine*** tablets in pregnancy (see 'Pregnancy and breastfeeding' in section 2).

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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 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 *Dihydrocodeine* tablets

Keep these tablets out of the sight and reach of children.

Do not use the tablets after the expiry date, which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not store your tablets above 25 °C.

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 *Dihydrocodeine* tablets contain

The active ingredient is dihydrocodeine tartrate.

Each tablet contains 60 mg, 90 mg or 120 mg of dihydrocodeine tartrate.

The other ingredients are lactose, hydroxyethylcellulose, cetostearyl alcohol, magnesium stearate and talc.

What *Dihydrocodeine* tablets look like and the contents of the pack

The tablets are white, capsule shaped and marked DHC followed by the strength (60, 90 or 120). In each bottle there are 56 tablets.

Marketing Authorisation Holder

Ennogen IP Ltd,
Unit G4, Riverside Industrial Estate,
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Manufacturer

Bard Pharmaceuticals Limited,
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