

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIHYDROCODEINE 30mg TABLETS

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you personally and you should 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, nurse or pharmacist.

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3. How Dihydrocodeine Tablets should be taken
4. Possible side effects
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1. WHAT DIHYDROCODEINE TABLETS ARE AND WHAT THEY ARE USED FOR

Dihydrocodeine belongs to a group of medicines known as opioid analgesics, which are used to relieve pain. Dihydrocodeine tablets are used for the relief of moderate to severe pain

2. BEFORE YOU TAKE DIHYDROCODEINE TABLETS

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

Dihydrocodeine Tablets should not be given if you:

- have ever had a reaction to or been told that you are allergic to dihydrocodeine, any other opioid analgesic or any of the other ingredients in the tablets (see section 6)
- have been told you have a tumour of the adrenal gland near your kidney called pheochromocytoma
- have severe problems with breathing
- are pregnant or breast-feeding.
- have increased pressure on the brain, have just had a head injury or if you are unconscious
- are suffering from acute alcoholism
- are at risk from a blocked intestine
- have severe stomach cramps caused by a condition known as biliary colic
- you have been told you have liver disease
- are suffering from severe diarrhoea

Speak to your doctor before you take Dihydrocodeine Tablets if you:

- are using drugs or have used drugs in the past as taking dihydrocodeine for a long time can lead to addiction.
- are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression
- suffer from asthma (your doctor may decide to administer Dihydrocodeine Tablets if your asthma is controlled. However, you should not be given this medicine if you are having an acute asthma attack)
- suffer from bronchitis (an inflammation of the lining of the tubes in the lungs, resulting in coughing spells accompanied by thick phlegm and breathlessness) or emphysema (a lung condition which leaves you struggling for breath)
- suffer from cor-pulmonale (a type of heart failure)
- are severely obese
- have a severely deformed spine
- are suffering from mental illness brought on by an infection
- have liver problems
- have kidney problems
- have problems with your bile duct
- suffer from an enlarged prostate gland (in men) or have difficulty passing urine
- have an under-active thyroid or adrenal gland
- have low blood pressure
- are in a state of severe shock
- are very run down
- have inflammatory bowel disease, such as Crohn's disease or ulcerative colitis or a blockage in the bowel
- suffer from convulsions (fits)

- are a child or elderly
- are feeling weak and feeble
- have 'myasthenia gravis' (tiredness and weakness of some muscles e.g. eyes, mouth and throat muscles)
- are a poor metaboliser of codeine

If any of the above apply to you, speak to your doctor, nurse or pharmacist before you take Dihydrocodeine Tablets.

Contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

It is very important that you inform your doctor if you are taking or have taken any other medicines, as some medicines may affect the way Dihydrocodeine Tablets work.

In particular, tell your doctor if you are taking any of the following:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression. You must also tell your doctor if you have stopped taking any of these or related medicines in the last two weeks
- tricyclic antidepressants, which are used in the treatment of depression
- tranquillising drugs or sleeping tablets such as diazepam, nitrazepam and temazepam
- medicines used to treat mental illnesses, including schizophrenia (e.g. chlorpromazine, haloperidol)
- medicines used for diarrhoea (e.g. loperamide, kaolin)
- medicines which are used as premedication before operations and after heart attacks such as atropine
- anaesthetics, particularly general anaesthetics (used in surgery to numb pain)
- antihistamines such as benadryl (used to treat allergies e.g. hayfever)
- sodium oxybate (used to treat narcolepsy)
- medicines used to treat nausea and vomiting, such as metoclopramide or domperidone
- mexiletine or quinidine, used to control heart rhythm
- cimetidine, used to treat stomach ulcers and indigestion

Food and drink and Dihydrocodeine Tablets

You should not drink alcohol whilst you are taking Dihydrocodeine Tablets, as they will increase its effects. Alcohol may increase the sedative effects of dihydrocodeine and make you very sleepy.

Pregnancy and breast-feeding

You should not be given dihydrocodeine if you are pregnant or think you might be pregnant unless you have discussed this with your doctor first. If you are given dihydrocodeine during pregnancy and become dependent on it, there is a risk that the new-born baby may also be dependent and suffer from withdrawal symptoms following delivery. If you are given dihydrocodeine during labour there is a risk that you could be sick and have breathing difficulties, or the baby could have difficulty starting breathing.

Do not breast-feed whilst taking Dihydrocodeine Tablets

Driving and using machines

You may feel drowsy and confused and you may develop blurred or double vision when you are taking Dihydrocodeine Tablets, so you should not drive or operate 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 <http://www.gov.uk/drug-driving-law>

3. HOW DIHYDROCODEINE TABLETS SHOULD BE TAKEN

The usual adult dose for Dihydrocodeine Tablets is one tablet every four to six hours.

The dose should be reduced in elderly patients. You may be given a reduced dose if you have kidney or liver problems. You may also be given a reduced dose if you suffer from any of the conditions listed above in the section headed 'Speak to your doctor before you take Dihydrocodeine Tablets if you:'



For children from four to twelve years the usual dose is 0.5-1.0 mg per kg of body weight every four to six hours.

The tablets are not recommended for children under four years of age.

Your doctor will decide the dose that is best for you. Always follow your doctor's instructions completely.

Also, follow any special instructions or warnings that appear on the label that the pharmacist has put on the package. If you do not understand or are in any doubt, ask your pharmacist.

Unless instructed differently, take your tablet(s) with a glass of water.

If you have been given a blister pack, to obtain a tablet, press on the tablet from the blister (or bubble) pushing it through the foil. Do not remove the tablet from the blister until you are ready to take it.

If you miss a dose of Dihydrocodeine Tablets

You should continue to take your medicine for as long as your doctor tells you to. If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER double the next dose to make up for the one missed. Do not stop taking the medicine without telling your doctor first.

If treatment with Dihydrocodeine Tablets is stopped

You should always check with your doctor before the treatment is stopped. It is possible that you could become dependent on dihydrocodeine and have withdrawal symptoms if it is stopped suddenly. This is more likely if you have a tendency for drug abuse or if you become dependent on Dihydrocodeine Tablets

4. POSSIBLE SIDE EFFECTS

Like all medicines, dihydrocodeine can cause side effects, but not everybody gets them. Tell your doctor or nurse immediately if you experience the following serious side effect:

- A severe allergic reaction, (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing). If you suffer such a reaction, you should not be given any more dihydrocodeine. Your doctor will decide on the appropriate treatment for allergic reactions. Difficulty in breathing and physical and psychological dependence are possible serious side effects. It is possible that you could become dependent on dihydrocodeine.

Side effects that are common include:

- drowsiness
- feeling sick or being sick
- constipation
- sweating.

Apart from constipation, these side effects tend to disappear with time.

Side effects that are less common include:

- dizziness
- feeling faint on standing up
- small pupils (in the eye)
- blurred vision
- double vision or other changes in vision
- mental clouding or confusion
- mood changes such as depression and sadness
- feeling extremely happy for no particular reason
- imagining things (hallucinations)
- nightmares
- headache
- vertigo (a feeling of dizziness or being light-headed)
- facial flushing
- dry mouth
- difficulty breathing
- stomach cramps
- difficulty or pain in passing urine
- passing more or less urine than usual
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- increased pressure within your head (raised intracranial pressure)
- hyperglycaemia (abnormally high levels of glucose in the blood)

- pancreatitis (inflammation of the pancreas)
- feeling unwell
- feeling tired
- hypothermia
- fever
- an enlarged spleen or swollen/enlarged lymph nodes
- anorexia
- uncontrolled muscle movements
- restlessness
- muscle rigidity
- palpitations (trembling, shaking, irregular heart beats)
- slower or faster pulse
- skin rash
- wheals or itching
- reduced sexual drive or impotence after long term use.
- inflammation of the pancreas

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 national reporting systems listed below.

United Kingdom

Yellow Card Scheme
www.mhra.gov.uk/yellowcard

Malta

ADR Reporting
www.medicinesauthority.gov.mt/adportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIHYDROCODEINE TABLETS

Keep out of the reach and sight of children.

Do not use Dihydrocodeine Tablets if the tablets show signs of discolouration.

Do not use Dihydrocodeine Tablets after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

REMEMBER this medicine is for YOU only. Never give it to anyone else. It may harm them, even if the symptoms are the same as yours. Unless your doctor tells you to, do not keep tablets that you no longer need. Give them back to the pharmacist. 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. FURTHER INFORMATION

What Dihydrocodeine Tablets contain

Dihydrocodeine Tablets contain the active ingredient Dihydrocodeine Tartrate. The tablets are available in one strength of 30mg.

Other ingredients are lactose, maize starch, magnesium stearate and povidone.

What Dihydrocodeine Tablets looks like and contents of the pack

Dihydrocodeine Tablets are white, circular tablets with DHC 30 and a breakline on one face and CP on the reverse

Dihydrocodeine Tablets are available in packs of 28, 30 or 100 tablets. Not all strengths and pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Dihydrocodeine 30mg Tablets	29831/0069

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