

# DIHYDROCODEINE 30 mg TABLETS

## Package leaflet: Information for the user

This medicine contains dihydrocodeine tartrate 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 is and what it is used for
2. What you need to know before you take Dihydrocodeine
3. How to take Dihydrocodeine
4. Possible side effects
5. How to store Dihydrocodeine
6. Contents of the pack and other information

### 1 What Dihydrocodeine is and what it is used for

This medicine has been prescribed for you for the relief of moderate to severe pain. It contains dihydrocodeine tartrate which 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, and how to do this safely.

### 2 What you need to know before you take Dihydrocodeine

**Do not take Dihydrocodeine if you:**

- are allergic (hypersensitive) to dihydrocodeine, or any of the other ingredients of this medicine
- suffer from problems with your breathing
- suffer from alcoholism
- have suffered a significant head injury
- are at risk of paralytic ileus (an inactive bowel) which may cause a blockage of the gut
- are having an asthma attack
- have an intolerance to some sugars
- 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.

#### Warnings and precautions

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 of Dihydrocodeine 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.

**Tell your doctor before you start to take this medicine if you:**

- suffer from liver or kidney problems
- are asthmatic, as dihydrocodeine should be given with care to persons liable to attacks and should not be given during an attack
- suffer from hypothyroidism (an underactive thyroid gland)
- suffer with prostatic hypertrophy (a problem with the prostate gland)
- are elderly or debilitated as the dosage should be reduced

- suffer with low blood pressure or are in shock
- suffer from convulsions (fits)
- have constipation or obstructive bowel disorders (symptoms may include constipation, diarrhoea, abdominal pain or discomfort)
- have inflammation of the pancreas (which causes severe pain in the abdomen and back)
- have problems with your gall bladder (urethral stricture)
- have a severe heart problem after long-term lung disease (severe cor pulmonale)
- are or have ever been addicted to drugs
- have adrenocortical insufficiency (symptoms include low blood pressure, weakness, nausea, vomiting, dizziness, skin discolouration, weight loss).

#### Other medicines and Dihydrocodeine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor if you are taking any of the following:

- medicines for allergies (antihistamines)
- any sedatives, such as temazepam or diazepam
- MAOI's (monoamine oxidase inhibitors) such as phenelzine for depression, or have taken any of these tablets within the last 14 days
- cyclizine, metoclopramide or domperidone, to prevent nausea or vomiting
- ciprofloxacin, an antibacterial used to treat infections of the chest, intestine and urinary tract
- antipsychotic drugs e.g. phenothiazines, chlorpromazine or haloperidol
- mexiletine, used to treat certain heart conditions
- ritonavir, used to treat HIV
- cimetidine, used to treat stomach ulcers
- tricyclic antidepressants e.g. amitriptyline
- anaesthetics (Important if you have recently or about to receive treatment where an anaesthetic may be used)
- medicines used for treating anxiety (anxiolytics).

Concomitant use of Dihydrocodeine and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Dihydrocodeine together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

#### Taking Dihydrocodeine with alcohol

Drinking alcohol during your treatment with these tablets may make you sleepy or enhance hypotensive effect and respiratory depression. If you are affected you should avoid drinking alcohol.

#### Pregnancy and breast-feeding

Do not take Dihydrocodeine 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 Dihydrocodeine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Dihydrocodeine 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 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.

The medicine 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.

#### Dihydrocodeine contains lactose and sodium

Patients who are intolerant to lactose should note that Dihydrocodeine tablets contain a small amount of 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.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

### 3 How to take Dihydrocodeine

Always take Dihydrocodeine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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.

The tablets should be swallowed preferably with a glass of water and are best taken after food.

The recommended dose is:

#### Adults

One tablet (30 mg) every 4 to 6 hours. However, your doctor may recommend a dosage individual to you.

#### The Elderly

A reduced adult dose is recommended; your doctor will advise you.

#### Use in children and adolescents

##### Children from 4 to 12 years of age

Your doctor will calculate the appropriate dose of Dihydrocodeine for your child based on the child's body weight. The dose should be taken every 4-6 hours.

##### Children under the age of 4 years

Dihydrocodeine is not recommended for use in children under 4 years of age.

#### If you take more Dihydrocodeine than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause difficulty in breathing, nausea, vomiting, fast heart rate, low blood pressure causing dizziness and a reduction in the size of the eye pupil which can all be exacerbated by also taking alcohol or other sedatives. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

#### If you forget to take Dihydrocodeine

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Dihydrocodeine

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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4 Possible side effects

Like all medicines, Dihydrocodeine can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression).

As with all strong painkillers, there is a risk you may become addicted or reliant on these tablets. Symptoms of restlessness and irritability may result when treatment is then stopped.

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

#### Common side effects: may affect up to 1 in 10 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 up to 1 in 100 people

- Diarrhoea, a condition where the bowel does not work properly (paralytic ileus)
- Mood changes
- Headache, confusion, a feeling of unusual weakness
- Hallucinations
- Blurred vision
- A feeling of dizziness or 'spinning', seizures, fits or convulsions
- Tingling or numbness
- Low blood pressure
- Decreased sexual drive
- Difficulty in passing urine

- Flushing of the skin
- Rash or itchy skin
- Shortness of breath
- Sweating
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance)
- A worsening in liver function tests (seen in a blood test)
- Constant acute abdominal pain.

#### Not known: frequency cannot be estimated from the available data

- Facial redness
- Slower heart rate
- Faster heart rate
- Palpitation
- A fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- Bowel spasm
- Depressed mood
- Contraction of the pupil of the eye
- Low body temperature
- Breathing difficulty in infants born to mothers who have received this medicine during pregnancy
- Swelling (oedema)
- Muscle rigidity
- Dependence and addiction (see section "How do I know if I am addicted?").

#### Drug Withdrawal

When you stop taking Dihydrocodeine, 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, 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](http://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

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 outer packaging. The expiry date refers to the last day of that month.

These tablets should be stored in a dry place below 25°C and protected from light, in the package or container supplied.

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. The other ingredients are maize starch, lactose monohydrate, povidone (E1201), sodium starch glycolate (Type A), magnesium stearate (E572) and colloidal silicon dioxide.

#### What Dihydrocodeine tablets look like and contents of the pack:

- Dihydrocodeine are white, flat, bevel edged tablets engraved 5B4 with a breakline
- The product is available in pack sizes of 7, 10, 14, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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