

PACKAGE LEAFLET: INFORMATION FOR THE USER**Dihydrocodeine 30mg Tablets BP**
(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, please 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 relief of moderate to severe pain including the pain of sciatica (nerve pain of the leg/back), joint and bone pain (osteoarthritis, rheumatoid arthritis and arthritis of the spine), nerve pain, pain following blood vessel disease, cancer or after operations.

It contains the Dihydrocodeine 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, how to do this safely.

2. What you need to know 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 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.

Do not take these tablets if you:

- are **allergic** (hypersensitive) to dihydrocodeine, opioid analgesics, or to any of other ingredients of this medicine (listed in section 6).
- have **difficulty breathing**, or other chronic lung disease
- have a **head injury** or a condition where there is **increased pressure in the skull** (may cause painful eyes, change in vision or headache behind the eyes)
- are having an **asthma attack**
- are **alcohol dependant**
- are at risk of **blocked intestines**

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- have **kidney** or **liver** problems
- have **low blood pressure** or are in **shock**
- have suffered with **allergies**
- have an **underactive thyroid** gland.
- have **enlarged prostate gland** and have **difficulty passing urine** and are **male**
- are **weak** due to illness
- have **adrenal gland** insufficiency (symptoms include low blood pressure, low blood sugar, muscle weakness, nausea, vomiting, dizziness, skin discolouration, weight loss)
- have **reduced lung capacity** (e.g. asthma or other conditions causing breathing difficulties)
- have a **convulsive disorder** (suffer from spasms/seizures)
- have inflammation or blockage in the **bowel** (symptoms may include constipation, diarrhoea, abdominal pain/discomfort)
- 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.

• are **elderly**

• are **feeling unusually light-headed** or **faint**

• have **inflammation of the pancreas** (which causes severe pain in the abdomen and back)

• have problems with your **gall bladder** or **bile duct**

• 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**.

! Other important warnings:

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

Children and adolescents

For **children under 12 years**, a more suitable dosage form is recommended.

Other medicines and Dihydrocodeine Tablets

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

- treating allergies (antihistamines)
- used to treat sickness (cyclizine, metoclopramide or domperidone)
- to aid sleep (hypnotics)
- treating anxiety (anxiolytics)
- treating depression such as monoamine oxidase inhibitors (MAOIs e.g. moclobemide, linezolid) or tricyclic antidepressants (amitriptyline, dosulepin)

- ‘antipsychotics’ used to treat mental illnesses including schizophrenia (e.g. chlorpromazine, sulpiride, haloperidol.)
- such as mexiletine (used to control heart rhythm)
- such as cimetidine (to treat stomach ulcers)
- used in anaesthesia (important if you have recently or are about to receive treatment where an anaesthetic may be used)
- used to treat HIV infections (e.g. ritonavir).

Concomitant use of Dihydrocodeine tablets 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 tablets 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.

Dihydrocodeine 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, breast-feeding and fertility**Pregnancy**

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.

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.

Breast-feeding

Do not take dihydrocodeine while you are breast-feeding as dihydrocodeine passes into breast milk and will affect your baby.

Driving and using machines

Dihydrocodeine tablets may reduce your ability to think clearly.

Effects such as ‘*pins and needles*’, dizziness, spinning sensations, visual disturbances, drowsiness, confusion, or hallucinations may occur.

Do not drive or operate machinery if affected.

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
 - to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.
- If you feel that your reactions are affected, do not operate machinery.

Dihydrocodeine Tablets contains Lactose

If you have been told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product.

Information on sodium content

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

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SAME SIZE ARTWORK

560 x180 mm
FrontFLAT DIMENSION = 180 x 560mm
FOLDED DIMENSION = 180 x 35mm

3. How to take Dihydrocodeine Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with **water, with or after food**.

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 recommended dose is:

- **Adults and children over 12 years:** One tablet every four to six hours or as directed by your doctor. Maximum dose in 24 hours is 180mg (6 tablets).
- **Children under 12 years:** Not recommended
- **Elderly:** Dosage is usually reduced in the elderly

If you take more Dihydrocodeine Tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include: very small pupils, feeling or being sick, feeling dizzy or light headed, irregular heartbeat.

If you forget to take Dihydrocodeine Tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before.

Do not take a double dose to make up for the forgotten dose.

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 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Dihydrocodeine tablets and contact your doctor immediately or go to your nearest emergency department if you notice the below serious side effects:

Uncommon (may affect up to 1 in 100 people):

- breathing more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect 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.

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

- signs of an allergic reaction such as itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing

Other side effects:

Common (may affect up to 1 in 10 people):

- constipation, feeling or being sick, abdominal pain, dry mouth
- drowsiness.

Uncommon (may affect up to 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).

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

- feeling elated
- extremely small pupils
- slow or fast heart rate, palpitations
- 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 section 2 'Pregnancy and breast-feeding').

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, 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, 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 Website: 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 this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date (Exp.) which is stated on the carton or bottle.
- Containers and blister carton: Do not store above 25°C. Store in the original container and keep the container tightly closed.
- 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 substance is dihydrocodeine tartrate
- The other ingredients are: maize starch, lactose monohydrate, povidone, sodium starch glycollate (Type A), magnesium stearate and colloidal anhydrous silica

What Dihydrocodeine Tablets look like and contents of the pack

- The tablets are white, flat, circular, bevel edged plain tablet with breakline
- They are available in the blister packs of 14, 28, 30, 56, 60, 84 and 100 tablets. Also available in containers of 25, 50, 100, 250, 500 and 1000 tablets
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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