PATIENT INFORMATION LEAFLET
DIHYDROCODEINE 30 MG TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine contains dihydrocodeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- 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. Do not pass it on to others, it may harm them, even if their symptoms 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.

1. WHAT DIHYDROCODEINE IS USED FOR

Dihydrocodeine tablets are used to relieve moderate to severe pain.

Dihydrocodeine 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

Do NOT take dihydrocodeine if:

- you are allergic (hypersensitive) to dihydrocodeine or any of the other ingredients of this medicine (listed in section 6)
- you have a medical condition where you find it difficult to breathe
- you are having an asthma attack
- you have a head injury or increased pressure in your head e.g. due to brain disease
- you have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus)
- you are addicted to alcohol

Warnings and precautions

- Do not take for longer than directed by your doctor or pharmacist.
- Avoid drinking alcohol while you are taking these tablets.
- Taking dihydrocodeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

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

- have kidney or liver problems
- have an under-active thyroid
- have asthma or allergic disorders
- are debilitated (in a weakened state)
- have low blood pressure or you are suffering from shock
- have an obstruction of inflammation of the gut or narrowing of the urethra (tube which passes urine from the bladder)
- have prostate or adrenal gland problems
- suffer from fits (convulsions)
- have a history of drug abuse
- have been told that you have an intolerance to some sugars. These tablets contain lactose monohydrate.

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 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.

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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.

Other medicines and dihydrocodeine

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

- hypnotics or sedatives (e.g. temazepam or diazepam)
- tricyclic antidepressants e.g. imipramine or antipsychotics (used to treat mental illness) e.g. clozapine.
- antihistamines that make you feel drowsy or dizzy e.g. chlorphenamine, promethazine
- mexiletine (used to treat certain heart conditions)
- monoamine oxidase inhibitors (MAOIs) or if you have stopped taking them within the last 14 days
- domperidone, metoclopramide or cyclizine (used to treat nausea and sickness)
- anaesthetics or alcohol
- cimetidine (used to treat ulcers)
- treating anxiety (anxiolytics)
- used to treat HIV infections (e.g. ritonavir)
- any other tablets or medicines including those not prescribed by your doctor.

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.

Pregnancy and breastfeeding

- Do not take dihydrocodeine tablets 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 Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
- 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 reduce your mental or physical ability (see section 4 for a full list of side effects). If affected do not drive or operate 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.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. HOW TO TAKE DIHYDROCODEINE

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.

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

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

These tablets are not recommended for children under 4 years of age.

Adults (including the elderly) and children over 12 years of age:

The usual dose is 1 tablet every 4-6 hours, or as directed by your doctor.

The dose may be reduced if you are elderly or have an under-active thyroid of severe kidney or liver problems.

If symptoms persist consult your doctor.

DO NOT EXCEED THE RECOMMENDED DOSE

If you forget to take a tablet take one as soon as you remember, unless it is almost time for your next dose. Never take two doses together.

IF YOU OR ANYONE ELSE TAKES TOO MUCH DIHYDROCODEINE

Contact your doctor immediately or go to your local hospital casualty department. Please take this leaflet, any remaining tablets and the container with you.

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.

4. POSSIBLE SIDE EFFECTS

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

Rare side effects

Signs of an allergic reaction such as skin rash, swelling of the lips, tongue or throat or difficulty breathing. **If affected stop taking the tablets and contact your doctor immediately or go to the nearest casualty department.**

Other side effects

- Rash, itching, sweating, facial flushing, tingling or numbness of the skin
- Dizziness, headache, vertigo, breathing difficulties,
- Muscle rigidity (at high doses)
- Visual disturbance, pinpoint pupils
- Drowsiness, mood changes, confusion, hallucination, euphoria
- Sexual dysfunction, gall bladder problems
- Dry mouth, nausea, vomiting, stomach pain, constipation
- Low blood pressure, slow or fast heartbeat (feeling your heart beat, fainting)
- Difficulty passing urine, fluid retention (which may cause swelling).
- Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

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 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 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 store above 25 °C. Keep in the original container or package. Keep the container tightly closed.

Do not use after the expiry date printed on the pack. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dihydrocodeine Tablets contain:

The active ingredient in each tablet is dihydrocodeine tartrate, 30 mg.

The other ingredients are maize starch, lactose monohydrate, Polyvinylpyrrolidone, sodium starch glycollate, colloidal silicon dioxide and magnesium stearate.

What Dihydrocodeine Tablets look like and contents of the pack:

The tablets are white, flat and round. Engraved with "DHC" and "30" on either side of a break line on one side and the M&A logo on the other.

They are available in packs of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168 tablets. Dispensing packs are also available.

Not all pack sizes may be marketed.

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