

DIHYDROCODEINE 30 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

- 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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 WHAT DIHYDROCODEINE IS AND WHAT IT IS USED FOR

- Dihydrocodeine is a painkiller
- Dihydrocodeine is used for the relief of moderate to severe pain.

2 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.

Take special care with Dihydrocodeine

Do NOT take Dihydrocodeine:

- for longer than directed by your prescriber
- regularly for a long time as it can lead to addiction, which may cause you to feel restless and irritable when you stop the tablets
- as a painkiller for headaches too often or for too long as it can make them worse.

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).

Taking 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).

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

Taking Dihydrocodeine with food and drink

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 these tablets if you are pregnant or likely to become pregnant. If you are breast-feeding do not take these tablets until you have spoken to your doctor.

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor for advice before taking any medicine.

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.

Important information about some of the ingredients of Dihydrocodeine

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.

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.

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

The usual 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.

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

You should continue to take these tablets for as long as your doctor tells you to. When you stop taking your tablets, you may feel anxious, depressed and restless, and have difficulty sleeping. If this happens, ask your doctor for advice.

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: affects 1 to 10 users in 100

- 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: affects 1 to 10 users in 1,000

- 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.

Side effects with frequency 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE DIHYDROCODEINE

Keep out of the reach and sight of children.

These tablets should be stored in a dry place below 20°C and protected from light, in the package or container supplied. Do not use Dihydrocodeine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

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:

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.

See outer packaging or the pharmacy label for contents i.e. the number of 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.

This leaflet was last revised: 02/2014

PL 00289/0228



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