Package leaflet – Information for the user

Dihydrocodeine 30mg Tablets

Dihydrocodeine Tartrate

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.

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

The name of your medicine is Dihydrocodeine 30mg Tablets (called dihydrocodeine throughout this leaflet). Dihydrocodeine contains a medicine called dihydrocodeine tartrate. It belongs to a group of medicines called analgesics (painkillers). It is used to relieve moderate to severe pain caused by conditions such as sciatica, Paget’s disease and shingles.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIHYDROCODEINE

Important things you should know about dihydrocodeine
- Do not take for longer than you doctor tells you
- 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 dihydrocodeine if you:
- are allergic (hypersensitive) to the active substance or any of the other ingredients in your medicine (listed in Section 6).
  Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.
- have liver disease
- have breathing problems, such as obstructive airways disease or respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected
- are having an asthma attack
- have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus)
- 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
- are addicted to alcohol
- have an intolerance to some sugars

Children
Co-dydramol must not be given to children

Do not take dihydrocodeine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking dihydrocodeine.

**Warnings and precautions**

*Take special care and check with your doctor before taking dihydrocodeine if:*

- You have severe kidney problems or long term liver problems
- You have asthma attacks
- You have problems with your thyroid gland (hypothyroidism)
- have constipation or obstructive bowel disorders
- have inflammation of the pancreas (which causes severe pain in the abdomen and back)
- have problems with your gall bladder
- have prostate problems
- have a severe heart problem after long-term lung disease (severe cor pulmonale)
- are or have ever been addicted to drugs

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

**Other medicines and dihydrocodeine**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because dihydrocodeine can affect the way some other medicines work. Also, some other medicines can affect the way dihydrocodeine works.

*Tell your doctor if you are taking any of the following medicines:*

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine
- Medicines which make you drowsy or sleepy (CNS depressants)
- Metoclopramide - used to stop you feeling sick (nausea) or being sick (vomiting)
- Medicines to treat psychiatric conditions or mental disorders (such as phenothiazines)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking dihydrocodeine.

**Dihydrocodeine with alcohol**

You should not drink alcohol while you are taking these tablets. This is because taking dihydrocodeine can change the way alcohol affects you.

**Pregnancy and breast-feeding**

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

**Driving and using machines**

You may feel dizzy or sleepy whilst taking dihydrocodeine. If this happens, do not drive or use any tools or machines.

**Dihydrocodeine tablets contain lactose**

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

**Changing or stopping treatment**

Chronic usage of dihydrocodeine may lead to tolerance and dependence. If you have taken regular daily doses of dihydrocodeine for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

3. **HOW TO TAKE DIHYDROCODEINE**
Always take dihydrocodeine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to

**Adults**
- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Take the tablets just after a meal
- The usual dose of dihydrocodeine is 1 tablet every 4 to 6 hours
- Elderly people may be prescribed a lower dose

**Children**
Do not give dihydrocodeine to children

**If you take more dihydrocodeine than you should**
- Tell your doctor or go to your nearest hospital casualty department straight away - even if you feel well.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken

**If you forget to take dihydrocodeine**
If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Important side-effects you should know about dihydrocodeine**
- Taking a painkiller for headaches too often or for too long can make them worse.
- 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

**Stop taking dihydrocodeine and see a doctor or go to a hospital straight away if:**
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria).
  This may mean you are having an allergic reaction to dihydrocodeine.
- You are breathing more slowly or weakly than expected (this could be a serious side effect known as respiratory depression)

**Talk to your doctor straight away if you notice the following serious side effect:**
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect, it affects less than 1 in 10,000 people

**Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:**

**Common side effects** (Probably affecting more than 1 in 100 people taking these tablets)
- 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 (Probably affecting fewer than 1 in 100 people taking these tablets)

- 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.
- 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).

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 internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10am to 2pm Mondays to Fridays) or fill in a paper form available from your local pharmacy.

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 shown on the pack. The expiry date refers to the last day of that month.
- Store your medicine in the original packaging
- Do not store above 25°C
- 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 30mg Tablets contain

- Each Dihydrocodeine 30mg Tablet contains 30mg of dihydrocodeine tartrate as the active ingredient.
- The other ingredients are maize starch, magnesium stearate, lactose monohydrate and colloidal hydrated silica.

What Dihydrocodeine 30mg Tablets look like and contents of pack
Dihydrocodeine 30mg Tablets are round, white tablets with Sterwin marked on one side and S25 on the other. They are supplied in cartons of 100 tablets.

The Marketing Authorisation Holder is Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

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Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK

This leaflet was last updated in October 2013.
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