

**PACKAGE LEAFLET: INFORMATION FOR THE USER****DIHYDROCODEINE 30MG TABLETS BP**  
**(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, 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**

Dihydrocodeine 30mg tablets contain the active substance dihydrocodeine tartrate.

Dihydrocodeine Tablets belong to a group of medicines called analgesics. These tablets are used for the 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.

**2. What you need to know before you take Dihydrocodeine Tablets**

**Do not take these tablets if you:**

- are **allergic** (hypersensitive) to dihydrocodeine, opioid analgesics, or to any of the ingredients in the tablet (see 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**
- have been told you have a tumour of the adrenal gland near your kidney called pheochromocytoma
- are pregnant or breast-feeding.
- have increased pressure on the brain, have just had a head injury or if you are unconscious
- have severe stomach cramps caused by a condition known as biliary colic
- you have been told you have liver disease
- are suffering from severe diarrhoea

**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 (in men)** and have **difficulty passing urine**
- are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression
- suffer from bronchitis (an inflammation of the lining of the tubes in the lungs, resulting in coughing spells accompanied by thick phlegm and breathlessness) or emphysema (a lung condition which leaves you struggling for breath)
- have 'myasthenia gravis' (tiredness and weakness of some muscles e.g. eyes, mouth and throat muscles)
- 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)
- have suffered from drug abuse

**! Other important warnings:**

- 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.

**Other medicines and Dihydrocodeine Tablets**

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

The following medicines can affect Dihydrocodeine:

Especially medicines:

- treating allergies (antihistamines)
- used to treat sickness (cyclizine, metoclopramide or domperidone)
- to treat anxiety and insomnia (e.g. diazepam, temazepam, chlordiazepoxide)
- treating depression such as monoamine oxidase inhibitors (MAOIs e.g. moclobemide, linezolid) or tricyclic antidepressants (amitriptyline, dosulepin)- taking or stopped taking in the past 2 weeks
- 'antipsychotics' used to treat mental illnesses including schizophrenia (e.g. chlorpromazine, halperidol)
- such as mexiletine and quinidine 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)
- such as loperamide or kaolin (used for diarrhoea)
- such as ciprofloxacin (used to treat bacterial infections)

**Dihydrocodeine tablets with food, drink and alcohol**

Alcohol should be avoided whilst taking dihydrocodeine tablets.

**Pregnancy, breast-feeding and fertility**

- Do not take Dihydrocodeine tablets during late pregnancy or whilst breast-feeding, unless advised by your doctor.
- Always ask your doctor or pharmacist for advice before taking any other medicine.

**Driving and using machines**

Dihydrocodeine tablets may reduce your ability to think clearly.

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

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

Dihydrocodeine Tablets

SAME SIZE ARTWORK

240 x 150 mm

Front

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.

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 medicine.

### **3. How to take Dihydrocodeine Tablets**

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

**Do not** drink alcohol whilst taking dihydrocodeine tablets.

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

Take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

#### **Doses:**

- **Adults:** One tablet every four to six hours or as directed by your doctor.
- **Children under 12 years:** Not recommended
- **Elderly:** Dosage is usually reduced in the elderly

You may be given a reduced dose if you have kidney or liver problems

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

Contact your nearest hospital A&E (casualty department) or your doctor immediately. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

**Signs of overdose** include nausea, vomiting, very small pupils, feeling dizzy or lightheaded, irregular heart beat, slow, shallow breathing and low blood pressure.

#### **If you forget to take a dose of Dihydrocodeine Tablets**

If you forget to take a dose, wait and take your next dose as usual.

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

#### **If you stop taking these tablets**

**Talk to your doctor** before you stop taking the tablets and follow their advice.

### **4. Possible side effects**

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

**Contact your doctor at once** if any signs of an allergic reaction occur such as:

- itchy skin rash
- swelling of the face, lips, tongue or throat
- breathing difficulty or swallowing

**Tell your doctor** if you notice any of the following side effects or notice any other effect not listed:

- **Gastrointestinal system** - constipation, feeling or being sick, abdominal pain, dry mouth, pancreatitis (inflammation of the pancreas)
- **Metabolism and nutrition disorders**- loss of appetite
- **Nervous system** - 'fits' or convulsions, uncontrolled muscle movements, 'pins and needles', tremors drowsiness, increased pressure within your head (raised intracranial pressure)
- **Musculoskeletal, connective tissue and bone disorders:** muscle rigidity
- **Ear**- vertigo ('spinning' sensation)
- **Respiratory System**- slow and shallow breathing
- **Skin** - rash, itchy skin, irregular raised patches, flushed face, sweating
- **Eyes**- blurred or double vision, extremely small pupils
- **Psychiatric effects**- depression, restlessness, drowsiness, changes of mood, confusion, hallucinations (seeing or hearing things that are not real), excitation, nightmares, unusual excitement in children
- **Heart**- slow or fast heart rate, palpitations, low blood pressure
- **Liver**- changes in liver enzyme levels
- **Urinary system** - pain and difficulty in passing urine and less frequent to do so
- **Reproductive system**- sexual dysfunction, reduced sexual drive or impotence after long term use.
- **Other**- water retention (oedema), general discomfort (malaise), tiredness, drowsiness, low body temperature

#### **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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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**

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road,  
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**Dihydrocodeine 30mg Tablets BP; PL 17907/0010**

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