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PACKAGE LEAFLET: INFORMATION FOR THE USER

Dihydrocodeine Elixir BP 10mg/5ml

Dihydrocodeine Tartrate

Read all of this leaflet carefully before you use Dihydrocodeine Elixir.

- 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 personally and you must not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dihydrocodeine Elixir is and what it is used for
2. Before you take Dihydrocodeine Elixir
3. How to take Dihydrocodeine Elixir
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1. What Dihydrocodeine Elixir is and what it is used for

Dihydrocodeine is a drug with powerful pain relieving properties. This medicine is used for the relief of moderate to severe pain. It can also be used to treat a cough.

2. Before you take Dihydrocodeine Elixir

You should not take Dihydrocodeine Elixir if you:

- are allergic (hypersensitive) to Dihydrocodeine or any of the ingredients of this medicine (listed in section 6 & 'Important information about some of the ingredients, column 2).
- suffer from breathing difficulties or are having an asthma attack
- have a lung infection
- are taking any Monoamine Oxidase Inhibitors (MAOIs) (a type of drug used to treat severe depression) or if you stopped taking them within the last two weeks
- are suffering from severe headaches or have suffered a head injury
- have difficulty opening your bowel
- have a tumour of the adrenal gland known as phaeochromocytoma
- have liver, kidney or stomach problems

This medicine should not be given to children under 4 years of age.

Take special care with Dihydrocodeine Elixir

Tell your doctor if you:

- are elderly or suffer from an under active or over active thyroid, liver or kidney problems, as the dose may need to be reduced
- have any breathing or lung problems
- have any prostate problems
- suffer from a convulsive disorder (fits) such as epilepsy
- are suffering from a problem that could cause paralysis of the small intestine (paralytic ileus)
- suffer from problems related to your adrenal gland, including Addison's disease
- suffer from under-active thyroid gland
- suffer from muscle wasting disease known as myasthenia gravis

- suffer with bowel problems
- suffer from problems with your pancreas
- have been told you suffer from a severe heart problem known as cor pulmonale
- have a cough that is producing mucus

Taking other medicines

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

Dihydrocodeine Elixir **must not** be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as Monoamine Oxidase Inhibitors (MAOI's).

Other medicines which may interact with with Dihydrocodeine Elixir include:

- medicines for sleeping problems and anxiety, such as chloral, diazepam, and barbiturates.
- CNS depressants (drugs that act on the brain and make you feel drowsy or faint). These include sleeping pills, anti-histamines (medicines used to treat allergies) that make you drowsy, medicines used to treat certain mental disorders, other pain killers or a general anaesthetic.
- alcohol

Taking Dihydrocodeine Elixir with food and drink

Dihydrocodeine Elixir should be taken with or after food. You are advised not to drink alcohol while being treated with Dihydrocodeine.

Pregnancy and breast-feeding

Dihydrocodeine Elixir should not be used during pregnancy and whilst breastfeeding, unless prescribed by your doctor. Dihydrocodeine is likely to cross the placenta and be present in breast milk and it may cause breathing problems in newborn babies.

Effects on the ability to drive and use machines

This medicine can affect your ability to drive and operate machinery. Do not drive or operate machinery if you feel drowsy or cannot think clearly.

This 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

- If you have been told by your doctor that you have an intolerance to some sugars (fructose, glucose, sucrose), contact your doctor before taking this medicine.
- This medicine contains 9.4% vol ethanol (alcohol), i.e. up to 380mg per 5ml dose, equivalent to 9.4ml beer, 3.9ml wine per dose. It is harmful for those suffering from alcoholism and has to be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

Continued overleaf

- Dihydrocodeine Elixir contains ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216) and methyl hydroxybenzoate (E218) which may cause an allergic (hypersensitive) reaction which could be delayed. Although rare, you may have difficulty breathing.

3. How to take Dihydrocodeine Elixir

Your doctor will decide on the dose and duration of your therapy. Always follow the instructions of your doctor or pharmacist.

Dihydrocodeine Elixir is for oral use and should be taken with or after food.

Moderate to severe pain:

Adults

One to three 5ml spoonfuls (10 - 30mg) every 4 - 6 hours

Elderly

A reduced dose is recommended

Children aged 4 to 12 years

0.5 to 1 mg per kg of body weight every 4 - 6 hours

Children under 4 years

Not recommended

Cough:

Adults

One 5ml spoonful (10mg) every 4 - 6 hours

Children aged 4 to 12 years

0.2 mg per kg of bodyweight every 4 - 6 hours

Children under 4 years

Not recommended

If you forget to take Dihydrocodeine Elixir

If you have missed a dose take it as soon as you remember unless it is nearly time for your next dose. Then continue your normal dose times. Do not take a double dose.

If you take more Dihydrocodeine Elixir than you should

If you take too much of your medicine seek immediate medical advice from your doctor or your nearest hospital.

If you stop taking Dihydrocodeine Elixir

You should not stop taking Dihydrocodeine Elixir until advised to do so by your doctor. If you stop treatment too suddenly you may experience symptoms of withdrawal such as stomach pains, feeling sick and feeling anxious. Your doctor will advise you how to stop your treatment with Dihydrocodeine Elixir.

4. Possible side effects

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

Repeated use of Dihydrocodeine can result in tolerance and addiction.

If any of the following symptoms occur contact your doctor or nearest accident and emergency department immediately. These are symptoms of a serious allergic reaction.

- sudden wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, fever
- collapse

Other side effects that may occur include:

- drowsiness
- headaches
- a feeling of dizziness or spinning
- feeling of being unwell

- hallucinations (seeing or hearing things that aren't real)
- changes in mood
- pin-point pupils
- sweating
- feeling faint when getting up from a seated position
- facial flushing
- constipation
- feeling sick (nausea)
- being sick (vomiting)
- skin reactions or itchy rashes
- difficulty passing urine
- stomach pain
- tingling, pricking or numbness of the skin ('pins and needles')
- restlessness
- dry mouth

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. Storing Dihydrocodeine Elixir

Keep out of the reach and sight of children.

Do not use Dihydrocodeine Elixir after the expiry date which is stated on the label and carton. 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 Elixir contains:

Active ingredient: Dihydrocodeine Tartrate BP 10mg in each 5ml of the flavoured base

Other ingredients: glycerol, sugar syrup (sucrose), citric acid monohydrate, alcohol, oxymel, sodium chloride, essence of limes soluble, essence of bitter orange soluble, strong tincture of ginger, E150 caramel, ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), methyl hydroxybenzoate (E218), purified water.

Each 5 ml dose of this elixir contains 0.38g of alcohol and 2.4g of sugar.

What Dihydrocodeine Elixir looks like and contents of the pack:

Dihydrocodeine Elixir is a thick brown liquid that smells of limes and ginger and is supplied in a 150ml amber glass bottle.

Marketing Authorisation Holder and Manufacturer:

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Product licence number: PL 0156/0092

Date of approval: January 2014

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