

## Thornton & Ross Codeine Phosphate 25mg/5ml Oral Solution

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

- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- 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.

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## 1. What is the medicine and what does it do?

The name of your medicine is Thornton & Ross Codeine Phosphate 25mg/5ml Oral Solution, which will be referred to as 'Codeine Phosphate Oral Solution' throughout this leaflet. This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other painkillers such as paracetamol.

### What is it for?

Codeine Phosphate Oral Solution can be used in two ways:

- In adults and children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.
- For the relief of the symptoms of diarrhoea in adults and children over 12 years.

## 2. Before you take the medicine

### Take special care with codeine

- Do not take for longer than directed by your doctor.
- In rare cases people can be at increased risk of developing overdose symptoms from codeine even when they have taken the recommended dose (people who are "ultra-rapid metabolisers" of codeine). If you experience severe effects including feeling sick, being sick, constipation, lack of appetite, feeling tired, sleeping longer than normal, shallow or slow breathing, then stop taking this medicine and seek immediate medical advice.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop.
- Taking a painkiller for headaches too often or for too long can make them worse.
- If you are elderly use with caution as the medicine can cause incontinence, diarrhoea, stomach pain and occasionally a blocked bowel.

### Do not take the medicine if the patient:

- Is **allergic** to codeine or any of the ingredients listed.
- Has **liver disease, severe kidney problems, a head injury, persistent headache, or raised head pressure.**
- Is having an **asthma attack** or has general shortage of breath.
- Is **under 12 years.**
- Has problems **emptying the bowel** or has other **problems** associated with the **bowel or intestine.**
- Suffers from **alcoholism.**
- **Do not take** the medicine for pain relief in **children and adolescents** (0-18 years of age) after **removal** of their **tonsils** or **adenoids** due to obstructive **sleep apnoea** syndrome.
- If you know that you **metabolise** very rapidly **codeine** into **morphine.**
- If you are **breastfeeding.**

- Has previously had an **addiction** to medicines containing **codeine** or **morphine.**

### Talk to your doctor or pharmacist if the patient has any of the following:

- Intolerance to some sugars.
- Kidney or liver problems (a reduced dose may be recommended by your doctor).
- A history of asthma or other breathing problems, including bronchitis.
- Low blood pressure.
- Irritable bowel syndrome (IBS) or other bowel problems.
- Abdominal pain.
- Myasthenia gravis (a disease of the muscles).
- Underactive thyroid or adrenal gland problems (a reduced dose may be recommended by your doctor).
- Gallstones or bile duct problems.
- Prostate problems.
- Problems passing urine.
- Irregular heartbeat.
- A history of epilepsy or fits.
- Or is suffering from shock.

Codeine is transformed to morphine in the liver by an enzyme.

Morphine is the substance that produces pain relief.

Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

### Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

### Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

### Talk to your doctor or pharmacist if the patient is already taking any of the following:

- Metoclopramide or domperidone (anti-nausea and vomiting medicines).
- Flecainide or mexiletine (for the treatment of irregular heartbeat).
- Any tranquillisers, antidepressants, sedatives or sleeping tablets.
- Any medicine used in the treatment of severe mental illness.

Concomitant use of this product 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 this product 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 breast feeding

Codeine Phosphate Oral Solution should not be used in pregnancy unless the doctor has told you to do so.

Use in late pregnancy may cause shallow breathing in the newborn baby and problems for the mother during labour.

Do not take codeine while you are breast feeding. Codeine and morphine passes into breast milk.

### Driving and using machinery

This medicine may affect your ability to drive or operate machinery. If you are feeling **dizzy** or **drowsy**, 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 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 this medicine.

- This medicine contains sucrose and ethanol (alcohol) as ingredients. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- It contains 4.25g sucrose per 5ml spoonful. This should be taken into account in patients with diabetes mellitus.
- This medicinal product contains 2.1 vol% ethanol (alcohol), i.e. up to 166mg per dose, equivalent to 4.2ml beer, 1.75ml wine per dose. Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breast feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

- Do not take this medicine if suffering from alcoholism or dependence on other opiates.
- It also contains sodium hydroxybenzoates which may cause allergic reactions (possibly delayed).

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## 3. How to take the medicine

**This medicine has been prescribed for you personally. Do not pass it on to others as it may harm them.**

**Dose:** Always take your medicine as prescribed by your doctor. The doctor may sometimes prescribe different doses to those listed below. **Always follow the doctor's instructions carefully.**

### The usual dose for the relief of pain is:

**Adults and Children over 12 years:** 1 or 2 x 5ml spoonfuls by mouth every 6 hours as needed. Do not take more than 8 x 5ml spoonfuls in any 24 hours.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Codeine Phosphate Oral Solution should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

**Elderly, frail, weak or infirm:** The doctor will prescribe the correct dose for you.

### The usual dose for diarrhoea is:

**Adults and children over 12 years:** 1 or 2 x 5ml spoonfuls by mouth every 6 hours as needed. Do not take more than 8 x 5ml spoonfuls in any 24 hours.

This medicine should not be taken for more than 3 days. If the diarrhoea does not improve after 3 days, talk to your doctor for advice.

Codeine Phosphate Oral Solution should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

**Elderly, frail, weak or infirm:** The doctor will prescribe the correct dose for you.

**If you take too much** see a doctor straight away.

**If you accidentally miss a dose**, take the normal dose as soon as you remember and then continue to take the medicine in the way you have been told. **Do not double up on the dose to make up for missed doses.**

## 4. Possible side effects

Like all medicines, Codeine Phosphate Oral Solution can cause side effects, although not everybody gets them.

### Important side effects

If you think that you have any of the following side effects or symptoms, stop using this medicine immediately and see a doctor as soon as possible.

- Allergic reactions including skin rashes, itching and blistering.

### Other possible side effects are:

- Hallucinations, mood changes, feeling restless or confused.
- Dizziness or vertigo, feeling unwell, drowsiness, disturbed sleep, headache or seizures.
- Pinpoint pupils or other problems with eyesight.
- Abnormal heartbeat.
- Feeling faint when standing up, low body heat, facial flushing or fluid retention (e.g. swollen ankles and feet).
- Slow, shallow breathing.
- Feeling or being sick, constipation, abdominal pain (including pain caused by inflammation of the pancreas (pancreatitis) or bile duct problems (biliary spasm)), loss of appetite or dry mouth.
- Sweating, muscle twitching or muscle stiffness.
- Ureteric spasm (urine tube problem causing abdominal or lower back pain), difficulty in passing urine.
- Low sexual urge.
- Taking a painkiller for headaches too often or for too long can make them worse.

### Taking codeine regularly for a long time can:

- Lead to addiction, or dependence, which might cause you to feel restless and irritable when you stop taking the syrup, or tolerance (the medicine loses its effect).
- Make Irritable Bowel Syndrome worse.

If any of the side effects become serious or if you notice any other effects not mentioned here, tell your doctor or pharmacist straight away. They will advise you what to do.

### 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) 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.

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## 5. How to store the medicine

Keep out of the sight and reach of children.

Do not use the medicine after any expiry date, which may appear on the label.

Medicines should not be disposed of via wastewater or household waste. Return any unused medicine to your pharmacist. These measures will help protect the environment.

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## 6. Further information

### What the medicine contains

The active substance is codeine phosphate 25mg per 5ml. The other ingredients are sodium methyl hydroxybenzoate (E219), ethanol, purified water and syrup (contains sucrose).

### What the medicine looks like

The medicine is an almost colourless syrupy liquid.

### Marketing Authorisation Holder and Manufacturer

Thornton and Ross Ltd., Huddersfield, HD7 5QH, England.

### This leaflet was last revised in

August 2018

PL 00240/6213R