

**Patient Information Leaflet**  
**Recodin syrup**  
**Chlorpheniramine Maleate 4mg and Codeine Phosphate 10mg**

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. See section d.

What is in this leaflet

- a. What Recodin syrup are and what it is used for
- b. What you need to know before you take Recodin syrup
- c. How to take Recodin syrup
- d. Possible side effects
- e. How to store Recodin syrup
- f. Further information

**This medicine contains codeine phosphate which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**a. What Recodin syrup and what it is used for**

This medicine has been prescribed for adults for relief of pain, relief of coughing and symptomatic relief of prolonged loose stools (diarrhoea) and for 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.

It contains codeine phosphate which belongs to a class of medicines called opioids, which are 'pain relievers'. It also contains chlorphenamine a antihistamine used to treat allergic conditions responsive to antihistamines including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions and insect bites. Also indicated for the symptomatic relief of itch associated with chickenpox.

This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

It can be used on its own or in combination with other painkillers such as paracetamol.

**b. What you need to know before you take Recodin syrup**

Do not take Recodin syrup if you:

- are allergic to codeine phosphate or any of the other ingredients of this medicine (listed in section f)
- have suffered a head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- have liver failure

- have severe breathing problems or other chronic lung disease
- are having an asthma attack - suffer with acute alcoholism
- have diarrhoea associated with either severe inflammation of the bowel or poisoning
- are at risk of blocked intestines
- are under 12 years old
- know that you metabolise very rapidly codeine into morphine - are breastfeeding.

**Do not use Recodin syrup** for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnea syndrome.

#### **Adolescents older than 12 years of age**

Codeine is not recommended in adolescents with compromised respiratory function for the treatment of cough and/or cold.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more of Recodin syrup to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs, such as phenelzine or isocarboxazid, are medicines used to treat depression
- have suffered from alcoholism, drug abuse or dependence or mental illness, irregular heartbeat or convulsions
- have recently undergone surgery of gastro-intestinal tract or urinary system.
- have been diagnosed as suffering from any of the following: - low blood pressure or are in shock
- deficiency in the activity of the thyroid gland
- enlarged prostate
- acute abdominal conditions
- gallstones or gall bladder disease
- severe weakness of muscles
- have liver or kidney problems
- have asthma or breathing problems
- have problems with your adrenal glands (such as Addison's disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
- have inflammatory bowel disease including severe bloody diarrhoea (pseudomembranous colitis) - are elderly or frail.

#### **Other important warnings:**

Taking a painkiller for headaches too often or for too long can make them worse.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cough. 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 or relieve their cough. 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.

**Children and adolescents:** 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 Apnea 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. Other medicines and Recodin syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Codeine is known to interfere with some medicines. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs (e.g. linezolid, moclobemide, selegiline etc) used to treat depression (refer to “Warnings and precautions” in section b above)
- phenobarbitone (medicine used for control of fits)
- hypnotics and alcohol
- other anti-diarrhoeal agents (e.g. loperamide, kaolin)
- anti-hypertensives (medicines used to control high blood pressure)
- cimetidine (to treat stomach ulcers)
- tricyclic antidepressants (eg amitriptyline)
- ciprofloxacin (antibacterial medicine)
- metoclopramide or domperidone (to prevent sickness)
- mexiletine or quinidine (to treat irregular heartbeats)
- antiviral medicines such as ritonavir
- medicines to treat allergies (antihistamines) that can cause drowsiness
- atropine (anticholinergic medicines)
- medicines which affect the nervous system such as chlorpromazine, diazepam, temazepam

- anaesthetics
- Opioid antagonists (buprenorphine, naltrexone, naloxone). Concomitant use of Recodin syrup 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 Recodin syrup 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.

### **Recodin syrup with food, drink and alcohol**

Do not drink alcohol whilst taking Recodin syrup. Alcohol may increase the sedative effects of Recodin syrup and make you very sleepy.

You can take the syrup regardless of food intake.

### **Pregnancy, breast-feeding and fertility**

Do not take Recodin syrup if you are pregnant or think you might be pregnant, unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Recodin syrup during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Recodin syrup while you are breastfeeding as codeine phosphate passes into breast milk and will affect your baby. Some women who are at increased risk of developing side effects at any dose may have higher levels of codeine in their breast milk.

If any of the following side effects develop in you or your baby stop taking this medicine and seek immediate medical advice; feeling sick, being sick, constipation, poor appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

### **Driving and using machines**

Do not drive or operate machinery because you may suffer from confusion, drowsiness, hallucinations (seeing, feeling or hearing things that are not there), blurred or double vision, fits or dizziness. This can affect driving or the operation of 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.

**Recodin syrup contain sucrose:** This medicine contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**c. How to take Recodin syrup**

Your prescriber should have discussed with you, how long the course will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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

**The recommended dose is:**

**For the relief of pain**

**Adults and children over 12 years:** 30-60 mg every four hours, when necessary to a maximum of 240 mg daily.

**For the relief of coughing Adults:** 15-30 mg three or four times daily.

**For the treatment of prolonged diarrhoea Adults:** 15-60 mg every four to six hours. Do not take more than 240 mg in 24 hours. A lower dosage may be needed if you are an older person who may have liver or kidney problems.

The 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.

**Use in children and adolescents**

Children below the age of 12 years

Recodin syrup should not be taken by children below the age of 12 years due to the risk of severe breathing problems.

**Children aged 12 years to 18 years**

In children and adolescents between 12 years and 18 years who have problems with their breathing, codeine is not recommended as this population may be more susceptible to breathing problems due to codeine.

**If you take more Recodin syrup than you should**

If you take more syrup, you may have symptoms such as feeling or being sick, depression, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate. Contact your doctor or pharmacist at once for advice.

**If you forget to take Recodin syrup**

If you forget to take a dose take it as soon as you remember and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Recodin syrup**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Prolonged use can lead to tolerance and dependence on the medicine. Taking codeine regularly for a long time can be habit forming, which might cause you to feel restless and irritable when

you stop the syrup. Your doctor will stop your syrup gradually to avoid you having withdrawal symptoms.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **d. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If the following happens, stop taking Recodin syrup and tell your doctor immediately or contact the casualty department at your nearest hospital

- allergic reactions (itch, hives, skin rash, redness, increase sweating, flushed face, difficulty breathing)
- increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes)
- fits (convulsions)

#### **Other side effects**

- confusion, dizziness, drowsiness, tiredness, changes in mood, nightmares, mental depression
- restlessness/excitement
- headache
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling sick (nausea), constipation, vomiting, dry mouth
- abdominal pain (may be caused by spasm of the bile ducts)
- low body temperature
- blurred or double vision, extremely small pupils
- palpitations, low blood pressure, low blood pressure on standing, slow or fast heart beat
- malaise (general discomfort)
- pain and difficulty in passing water and a less frequent need to do so
- uncontrolled muscle movements and rigidity
- decrease in sex drive.

Tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)

**Unknown frequency:** dependence and addiction (see section “How do I know if I am addicted?”).

#### **Drug Withdrawal**

When you stop taking Recodin syrup, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

#### **How do I know if I am addicted?**

If you notice any of the following signs whilst taking Recodin syrup, it could be a sign that you have become addicted.

- you need to take the medicine for longer than advised by your prescriber
- you feel you need to use more than the recommended dose

- you are using the medicine for reasons other than prescribed
- when you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber

**e. How to store Recodin syrup**

- Do not store above 30°C.
- Protect from light
- Keep out of reach of children.
- Do not use this medicine after the expiry date which is stated on the label, carton and blister after “EXP”. The expiry date refers to the last day of that month.
- Do not put them in another container. For container packaging replace the cap securely after use.
- 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.

**f. Further information**

**What Recodin syrup contains**

The active substances are codeine phosphate and Chlorphenamine maleate.

Each 5ml contains Chlorpheniramine Maleate 4 mg and Codeine Phosphate 10 mg.

The other ingredients are Carmellose sodium, Sodium methyl paraben, Sodium propyl paraben, Sucrose, Propylene glycol, Sodium saccharin, Menthol, Chocolate brown colour.

**What Recodin syrup look like and contents of the pack**

Light brown coloured, flavoured syrup filled in amber coloured PET bottle and sealed with ROPP caps.

100ml amber PET bottles and sealed with ROPP caps.

**MANUFACTURED BY**

RENE INDUSTRIES LIMITED

Plot 680, Kamuli, Kireka

P.O Box 6034, Kampala, Uganda



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