

(LogoAccord)

## Package leaflet: Information for the patient

### Lynlor 5mg, 10mg and 20mg Capsules, hard

oxycodone hydrochloride

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

**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 4.

#### What is in this leaflet

1. **What Lynlor is and what it is used for**
2. **What you need to know before you take Lynlor**
3. **How to take Lynlor**
4. **Possible side effects**
5. **How to store Lynlor**
6. **Contents of the pack and other information**

#### 1. What Lynlor is and what it is used for

This medicine has been prescribed for you to treat severe pain, which can only be adequately managed with opioid analgesics. It contains oxycodone hydrochloride, which is a centrally acting, strong painkiller which belongs to a class of medicines called opioids. This medicine has been prescribed for 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 doctor should have explained how long you will be taking it for, when it is appropriate to stop, and how to do this safely.

#### 2. What you need to know before you take Lynlor

##### Do not take Lynlor if you:

- are **allergic** to oxycodone, or any of the other ingredients of the capsules (listed in section 6)
- have **breathing problems**, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected
- have a condition where the **small bowel** does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen
- have a **heart problem** after long-term lung disease (cor pulmonale)
- have **increased carbon dioxide levels in the blood**. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache
- have **moderate to severe liver problems**. If you have other long-term liver problems you should only take these capsules if recommended by your doctor
- have ongoing problems with **constipation**.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Lynlor if you:

- are elderly or weakened

- have an under-active thyroid gland (hypothyroidism), as you may need a lower dose
- have myxoedema (a thyroid disorder with dryness, coldness and swelling ['puffiness'] of the skin affecting the face and limbs)
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased
- have low blood pressure (hypotension)
- have low blood volume (hypovolaemia). This can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting
- feel very lightheaded or faint
- have a mental disorder following use of certain medicines (toxic psychosis)
- have inflammation of the pancreas (which causes severe pain in the abdomen and back), have problems with your gall bladder or bile duct
- have colicky abdominal pain or discomfort
- have inflammatory bowel disease
- have an enlarged prostate gland, which causes difficulty in passing urine (in men)
- have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick), e.g. Addison's disease
- have severely impaired lung function. Symptoms may include breathlessness and coughing
- have long term pain unrelated to cancer
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea
- have kidney or liver problems.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as these could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

#### *Tolerance, dependence and addiction*

Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Taking this medicine regularly, particularly for a long time, can lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Your doctor should have explained how long you will be taking Lynlor for, when it is appropriate to stop, and how to do this safely. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Lynlor if you:

- or anyone in your family have ever abused or been dependent on opioids, alcohol, prescription medicines, or illegal drugs ('addiction')
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- 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 Lynlor to get the same level of pain relief, as this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

See section 4 'How do I know if I am addicted?' for signs that you may have become dependent or addicted.

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

Do not inject Lynlor. This can cause serious side effects including tissue death at the site of injection, infection, inflammation of the lungs and damage to the heart which may be fatal.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital that you are taking these capsules. Your doctor may adjust your dose.

You may experience hormonal changes while taking these capsules. Your doctor may want to monitor these changes.

#### **Sleep-related breathing disorders**

Lynlor can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

#### **Children and adolescents**

Lynlor has not been investigated in children under 12 years. Safety and efficacy have not been established and therefore use in children under 12 years of age is not recommended.

#### **Other medicines and Lynlor**

Taking Lynlor at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:

- other medicines used to treat pain known as opioids (such as codeine or morphine)
- medicines used to treat epilepsy (gabapentinoids) such as pregabalin
- medicines used to treat anxiety
- medicines used to make you feel sleepy (such as benzodiazepines)
- medicines used to treat psychiatric or mental disorders (such as phenothiazines)
- anaesthetics
- muscle relaxants
- medicines used to treat high blood pressure
- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not take Lynlor if you are currently taking this type of medicine, or have taken this type of medicine in the last two weeks.

Because of this, your doctor will only prescribe Lynlor where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately.

Taking Lynlor with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary,

rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C, seeing or hearing things that are not real (hallucinations), loss of consciousness, fast heartbeat, blood pressure changes, lack of coordination, stiffness, feeling or being sick, and diarrhoea. Contact your doctor when experiencing such symptoms, as they may reduce your dose of Lynlor.

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

Tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to adjust your dose:

- a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline
- medicines used to treat allergies, such as cetirizine, fexofenadine or chlorphenamine
- medicines used to treat Parkinson's disease
- antibiotics such as clarithromycin, erythromycin or telithromycin
- antifungal medicines such as ketoconazole, voriconazole, itraconazole and posaconazole
- medicines used to treat HIV known as protease inhibitors, such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir
- cimetidine, a medicine used to treat stomach ulcers
- rifampicin, a medicine used to treat tuberculosis
- medicines used to treat seizures, fits or convulsions such as carbamazepine and phenytoin
- a herbal remedy used to treat depression known as St. John's Wort (also known as *Hypericum perforatum*)
- quinidine, a medicine used to treat an irregular heartbeat.

### **Lynlor with food, drink and alcohol**

Drinking alcohol during your treatment with these capsules may make you sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're taking Lynlor capsules.

You should avoid drinking grapefruit juice during your treatment with this medicine.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Pregnancy**

Do not take Lynlor if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take Lynlor during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Use of oxycodone during childbirth can cause breathing problems in the newborn.

#### **Breast-feeding**

Do not take Lynlor while you are breastfeeding as oxycodone passes into breast milk and will affect your baby.

### **Driving and using machines**

This medicine may cause a number of side effects such as drowsiness or dizziness which may affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full list of side effects). These are usually most noticeable when you first start taking Lynlor, or when changing to a higher dose.

- 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 your doctor 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.

### **Information on sodium content**

This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

## **3. How to take Lynlor**

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from taking Lynlor, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also 'If you stop taking Lynlor'). They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

### **Adults and adolescents over 12 years**

The usual starting dose is one 5mg capsule every 6 hours. However, your doctor will prescribe the appropriate dose and frequency of administration required to treat your pain.

If you find that you are still in pain whilst taking these capsules, discuss this with your doctor.

### **Method of use**

Lynlor capsules should be swallowed whole with a sufficient amount of liquid.

Lynlor should not be taken with alcoholic beverages.

You must only take the capsules by mouth. The capsule contents should never be injected as this may lead to serious side effects, which may be fatal (see section 2 'Warnings and precautions').

### **Adults with renal or liver impairment**

The usual starting dose is half the recommended dose for adults. Your doctor will prescribe the appropriate dose based on your clinical situation and by using a more suitable formulation if available.

### **Use in children**

Lynlor is not recommended for children under 12 years of age.

### **If you take more Lynlor than you should**

If you have taken more Lynlor than prescribed, or if someone accidentally swallows your capsules, you should inform your doctor or your local poison control centre immediately. The following symptoms may occur: constricted pupils, depressed breathing, muscle weakness, drowsiness and drop in blood pressure. In severe cases, a brain disorder (known as toxic leukoencephalopathy); circulatory collapse, mental and motor inactivity, unconsciousness, slowing of the heart rate and accumulation of water in the lungs may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case should you expose yourself to situations requiring elevated concentration e.g. driving a car.

### **If you forget to take Lynlor**

If you miss a dose you should take the next dose as soon as you remember and then carry on as before. Do not take two doses within 4 hours.

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

### **If you stop taking Lynlor**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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.

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

#### 4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are rare. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and Lynlor'). **Tell your doctor immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

**Very common** (may affect more than 1 in 10 people):

- 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 capsules or when your dose is increased, but it should wear off after a few days)
- Dizziness
- Headache
- Itchy skin.

**Common** (may affect up to 1 in 10 people):

- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea
- Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal thoughts or dreams
- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex
- Rash
- Sweating.

**Uncommon** (may affect up to 1 in 100 people):

- Withdrawal symptoms (see section 'Drug withdrawal')
- Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste or unpleasant taste
- A feeling of dizziness or spinning (vertigo), hallucinations, mood changes, unpleasant or uncomfortable mood, a feeling of extreme happiness, disorientation, restlessness, agitation
- Generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, blurred or impaired vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions or spasms
- Difficulty or pain in passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test)
- Fast, irregular heartbeat, palpitations, a feeling of lightheadedness, dizziness, flushing of the skin
- Dehydration, thirst, chills, swelling of the hands, ankles or feet
- Dry skin, severe flaking or peeling of the skin
- Redness of the face, reduction in size of the pupils in the eye, high temperature
- A need to take increasingly higher doses of the capsules to obtain the same level of pain relief (tolerance)
- Colicky abdominal pain or discomfort

- A worsening of liver function tests (seen in a blood test).

**Rare** (may affect up to 1 in 1,000 people):

- Low blood pressure
- A feeling of 'faintness' especially on standing up
- A raised, itchy rash (hives).

**Not known** (frequency cannot be estimated from the available data):

- Dependence and addiction (see section 'How do I know if I am addicted?')
- An increased sensitivity to pain
- Aggression
- Tooth decay
- Absence of menstrual periods
- A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools
- A problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- Sleep apnoea (breathing pauses during sleep)
- Long term use of Lynlor capsules during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

### **Drug Withdrawal**

When you stop taking Lynlor, 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 Lynlor, it could be a sign that you have become dependent or addicted.

- You need to take the medicine for longer than advised by your doctor
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, it is important you talk to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3 'If you stop taking Lynlor').

### **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.

## **5. How to store Lynlor**

Keep this medicine out of the sight and reach of children. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them, particularly for children.

Do not take this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°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 Lynlor contains**

- The active substance is oxycodone hydrochloride.  
Lynlor 5mg Capsules, hard: Each capsule contains 5mg oxycodone hydrochloride.  
Lynlor 10mg Capsules, hard: Each capsule contains 10mg oxycodone hydrochloride.  
Lynlor 20mg Capsules, hard: Each capsule contains 20mg oxycodone hydrochloride.
- The other ingredients are: Capsule content: microcrystalline cellulose, magnesium stearate.  
Capsule shell: Gelatine, sodium laurilsulfate, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigotine (E132). Printing ink: shellac, iron oxide black (E172), potassium hydroxide.

### **What Lynlor looks like and contents of the pack**

Lynlor 5mg: Hard capsules, 14.4 mm in length, with a dark pink body marked with '5' and a brown cap marked with 'OXY'.

Lynlor 10mg: Hard capsules, 14.4 mm in length, with a white body marked with '10' and a brown cap marked with 'OXY'.

Lynlor 20mg: Hard capsules, 14.4 mm in length, with a light pink body marked with '20' and a brown cap marked with 'OXY'.

Pack size: Non child resistant blisters: 56 capsules.

### **Marketing Authorisation Holder and Manufacturer**

Accord, Barnstaple, EX32 8NS, UK

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