

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Ropirade XL 2mg Prolonged-release Tablets Ropirade XL 4mg Prolonged-release Tablets Ropirade XL 8mg Prolonged-release Tablets**

Ropinirole

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any more questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Don't pass it on to other people. It may harm them even if their symptoms seem to be the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Ropirade XL is and what it is used for
2. Before you take Ropirade XL
3. How to take Ropirade XL
5. Possible side effects
6. How to store Ropirade XL
7. Further information

#### **1. WHAT ROPIRADE XL IS AND WHAT IT IS USED FOR**

Ropirade XL prolonged-release tablets are used to treat Parkinson's disease. The active ingredient in Ropirade is ropinirole, which belongs to a group of medicines called dopamine agonists. Dopamine agonists affect the brain in a similar way to a natural substance called dopamine.

People with Parkinson's disease have low levels of dopamine in some parts of their brains. Ropinirole has effects similar to those of natural dopamine, so it helps to reduce the symptoms of Parkinson's disease.

#### **2. BEFORE YOU TAKE ROPIRADE XL**

##### **Do not take Ropirade XL**

- if you are allergic (hypersensitive) to ropinirole or any of the other ingredients of Ropirade XL; (see section 6)
- if you have serious kidney disease
- if you have liver disease.

Tell your doctor if you think any of these may apply to you.

##### **Take special care with Ropirade XL**

Your doctor needs to know before you take Ropirade XL:

- if you are pregnant or think you may be pregnant
- if you are breast feeding
- if you are under 18 years old
- if you have a serious heart complaint
- if you have a mental health problem
- if you have a history of any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour)

Tell your doctor if you think any of these may apply to you. Your doctor may decide that

Ropirade XL isn't suitable for you or that you need extra check-ups while you're taking it. Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

### **Using other medicines**

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

Some medicines can affect the way Ropirade XL works, or make it more likely that you will have side effects. Ropirade XL can also affect the way some other medicines work.

- the anti-depressant fluvoxamine
- HRT (hormone replacement therapy)
- the antibiotic ciprofloxacin or enoxacin
- medication for other mental health problems, for example sulpiride
- metoclopramide, which is used to treat nausea and heartburn
- cimetidine, used in the treatment of stomach ulcers
- theophylline, used for asthma, bronchitis or air trapped in the body (emphysema)
- any other medicine for Parkinson's disease.

Tell your doctor if you are taking, or have recently taken, any of these.

### **Taking Ropirade XL with food and drink**

Swallow the tablets whole with a glass of water. You can take Ropirade XL with or without food, as you prefer.

You should not drink alcohol while you are taking Ropirade XL.

Tell your doctor or nurse if you start smoking, or give up smoking, while you're taking Ropirade. Your doctor or nurse may need to adjust your dose.

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

Tell your doctor immediately if you are pregnant, if you think you might be pregnant, or if you are planning to become pregnant. Your doctor will also advise you if you are breast feeding or planning to do so. Your doctor may advise you to stop taking Ropirade XL.

Ask your doctor or pharmacist for advice before taking any medicine.

Ropirade XL is not recommended if you are pregnant, unless the doctor advises that the benefit of you taking Ropirade XL is greater than the risk to your unborn baby.

Ropirade XL is not recommended if you are breast feeding, as it can affect your milk production.

### **Driving and using machines**

Do not drive because Ropirade XL can make you feel drowsy. It can make people feel extremely sleepy and it sometimes makes people fall asleep very suddenly without warning.

Do not operate or use any tools or machinery. Do not drive, do not operate machines and do not put yourself in any situation where feeling sleepy or falling asleep could put you (or

other people) at risk of serious injury or death. Don't take part in these activities until you are no longer affected.

Talk to your doctor if this causes problems for you.

### **Important information about some of the ingredients of Ropirade XL**

Ropirade XL 2 mg prolonged-release tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Ropirade XL 4 mg prolonged-release tablet contain the colouring agent sunset yellow, which may cause allergic reactions.

### **3. HOW TO TAKE ROPIRADE XL**

Always take Ropirade XL exactly as your doctor has told you to. You should check with your doctor or pharmacist if you're not sure.

The product is a prolonged-release tablet and should not be taken if the tablet is broken or damaged.

You may be given Ropirade XL on its own to treat the symptoms of your Parkinson's disease or you may be given Ropirade XL as well as another medicine called L-dopa (also called levodopa). If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you first start taking Ropirade XL. Tell your doctor if this happens, as your doctor may need to adjust the dose of the medicines you are taking.

The usual starting dose of Ropirade XL prolonged-release tablets is 2 mg once daily for the first week. Your doctor may increase your dose to 4 mg of Ropirade XL prolonged-release tablets once daily, from the second week of treatment. If you are very elderly, your doctor may increase your dose more slowly. After that, the doctor may adjust your dose until you are taking the dose that is best for you. Some people take up to 24 mg of Ropirade XL prolonged-release tablets each day.

Do not give Ropirade XL to children. Ropirade XL is not normally prescribed for people under 18.

It may take a while to find out the best dose of Ropirade XL for you.

### **Taking your dose of Ropirade XL**

Take Ropirade XL once a day, at the same time each day.

Swallow your Ropirade XL prolonged-release tablet(s) whole, with a glass of water.

Do not break, chew or crush the prolonged-release tablet(s) - if you do, there is a danger you could overdose, because the medicine will be released into your body too quickly.

### **If you are switching from ropinirole film-coated (immediate release) tablets**

Your doctor or nurse will base your dose of Ropirade XL on the dose of ropinirole you were taking. You will take the same or similar daily dose of Ropirade XL to your previous dose of ropinirole but you will only take Ropirade XL once a day.

Take your ropinirole as normal the day before you switch. Then take your Ropirade XL on the next day and don't take any more ropinirole.

### **If you take more Ropirade XL than you should**

Contact a doctor or pharmacist immediately. If possible, show them the Ropirade XL pack.

Someone who has taken an overdose of Ropirade XL may have any of these symptoms: feeling sick (nausea), being sick (vomiting), dizziness (a spinning sensation), feeling drowsy, mental or physical tiredness, fainting, hallucinations.

**If you forget to take Ropirade XL**

Don't take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you have missed taking Ropirade XL for more than a few days, ask your doctor for advice on how to start taking it again.

**If you stop taking Ropirade XL**

Do not stop taking Ropirade XL without advice.

Take Ropirade XL for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you suddenly stop taking Ropirade XL your Parkinson's disease symptoms may quickly get much worse.

If you need to stop taking Ropirade XL your doctor will reduce your dose gradually.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ropirade XL can have side effects, although not everyone gets them.

If you're worried about side effects, talk to your doctor.

***Very common side effects*** (affects more than 1 in 10 people taking Ropirade XL):

- fainting
- feeling drowsy
- feeling sick (nausea)

***Common side effects*** (affects more than 1 in 100 people taking Ropirade XL):

- hallucinations (sensing things that are not real)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- constipation
- swelling of the legs, feet or hands

***Uncommon side effects*** (affects more than 1 in 1,000 people taking Ropirade XL):

- feeling dizzy or faint, especially when you stand up suddenly (this is caused by a drop in blood pressure)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)
- feeling very sleepy during the day (extreme somnolence)

You may experience the following side effects:

- changes in liver function, which have shown up in blood tests
- allergic reactions such as red, itchy swellings on the skin (hives), swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash or intense itching
- inability to resist the impulse to perform an action that could be harmful to you or others, which may include:

- strong impulse to gamble excessively despite serious personal or family consequences
- altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
- uncontrollable excessive shopping or spending
- binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

**Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms**

#### **If you're taking Ropirade XL with L-dopa (for Parkinson's disease)**

People who are taking Ropirade XL with L-dopa may develop other side effects over time:

- uncontrollable movements (dyskinesia) are a very common side effect. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking
- feeling confused is a common side effect

If any of the side effects get serious or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE ROPIRADE XL**

Keep Ropirade XL out of the sight and reach of children.

Do not use Ropirade XL after the expiry date (e.g. Exp) shown on the carton, blister and bottle. The expiry date refers to the last day of that month.

Store Ropirade XL below 25°C.

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 Ropirade XL contains**

The active substance in Ropirade is ropinirole.

Each prolonged release tablet contains ropinirole hydrochloride equivalent to 2 mg, 4 mg or 8 mg ropinirole.

The other ingredients are:

- *tablet core:* Ammonio methacrylate copolymer, Type B, hypromellose, sodium laurilsulfate, copovidone, magnesium stearate.
- *tablet coating:*

2 mg	Hypromellose (E464), iron oxide red (E172), lactose monohydrate, titanium dioxide (E171), triacetin
4 mg	Macrogol 400, hypromellose (E464), sunset yellow (E110), titanium dioxide (E171), indigo carmine (E132)
8 mg	Hypromellose (E464), iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172), macrogol 400, titanium dioxide (E171)

#### **What Ropirade XL looks like and contents of the pack**

Ropirade XL 2 mg: pink prolonged-release round biconvex tablets  $6.8 \pm 0.1$  mm in diameter and  $5.5 \pm 0.2$  mm in thickness.

Ropirade XL 4 mg: light brown prolonged-release oval biconvex tablets with dimensions  $12.6 \times 6.6 \pm 0.1$  and  $5.3 \pm 0.2$  mm in thickness.

Ropirade XL 8mg: red prolonged-release oval biconvex tablets with dimensions  $19.2 \times 10.2 \pm 0.2$  mm and  $5.2 \pm 0.2$  mm in thickness.

**All strengths** are supplied in white opaque PVC/PCTFE-Aluminium foil blisters and white opaque HDPE bottles with child resistant screw cap and mounted desiccant.

Pack sizes:

Ropirade XL 2 mg: 7, 14, 21, 28, 30, 56, 60, 84, 90, 98, 100, 120, 168 tablets.

Ropirade XL 4 mg: 14, 28, 30, 56, 60, 84, 90, 98, 100, 120, 168 tablets.

Ropirade XL 8 mg: 14, 28, 30, 56, 60, 84, 90, 98, 100, 120, 168 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

**Manufacturer:**

Pharmathen S.A 6<sup>th</sup> Dervanakion Str, Athens, Pallini 15351, Greece

Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300, Greece

STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

Sanico NV, Veedijk 59, B-2300 Turnhout, Belgium

LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero (Modena), Italy

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

**This medicinal product is authorised in the Member States of the EEA under the following names:**

FR: ROPINIROL STADA LP 2 mg, 4 mg, 8 mg comprimé à libération prolongée

AT: Ropinirol STADA 2 mg, 4 mg, 8 mg Retardtabletten

BE: Ropinirole Retard EG 2 mg, 4 mg, 8 mg tabletten met verlengde afgifte

LU: Ropinirole Retard EG 2 mg, 4 mg, 8 mg comprimés à libération prolongée

CZ: Ropinirole STADA 2mg, 4 mg, 8 mg tablety s prodlouženým uvolňováním

DE: Ropinirol AL 2 mg, 4 mg, 8 mg Retardtabletten

DK: Ropinostad 2 mg, 4 mg, 8 mg

FI: Ropinirol STADA 2 mg, 4 mg, 8 mg

IE: Ropirade XL 2 mg, 4 mg, 8 mg prolonged-release tablets

SK: Ropinirol ER STADA 2 mg, 4 mg, 8 mg

**This leaflet was last approved in September 2012.**