PACKAGE LEAFLET: INFORMATION FOR THE USER

ROPINIROLE 0.25mg FILM-COATED TABLETS
ROPINIROLE 0.5mg FILM-COATED TABLETS
ROPINIROLE 1.0mg FILM-COATED TABLETS
ROPINIROLE 2.0mg FILM-COATED TABLETS

Ropinirole

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

1. WHAT ROPINIROLE IS AND WHAT IT IS USED FOR

The active ingredient in ROPINIROLE FILM-COATED TABLETS is Ropinirole, which belongs to a group of medicines called **dopamine agonists**. Dopamine agonists act in a similar way to a natural substance called dopamine in the brain.

ROPINIROLE is used to treat Parkinson's disease. 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.

ROPINIROLE is used to treat the symptoms of moderate to severe Restless Legs Syndrome.

Restless legs syndrome (RLS) is also called Ekbom syndrome. People with restless legs syndrome have an irresistible urge to move their legs, and sometimes their arms and other parts of their bodies. Usually, they have unpleasant sensations in their limbs - sometimes described as 'crawling' or bubbling' – which can begin as soon as they sit or lie down, and are relieved only by movement. So they often have problems with sitting still and especially with sleeping.

ROPINIROLE relieves the unpleasant sensations, and so reduces the urge to move the legs and other limbs.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ROPINIROLE

Do not take ROPINIROLE

- if you are **allergic** to the active ingredient , ropinirole, or any of the other ingredients of ROPINIROLE (listed in section 6).
- if you have serious **liver disease**

- if you have a **serious kidney disease**

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

Warnings and precautions
Tell your doctor or pharmacist before you start to taking ROPINIROLE if you:

- are **pregnant** or think you may be pregnant
- are **breast-feeding**
- are **under 18 years old**
- have liver disease
- have a **serious heart complaint**
- have a **serious mental health problem**
- have experienced any **unusual urges and /or behaviours** (such as excessive gambling or excessive sexual behaviour)
- have an **intolerance to some sugars** (such as lactose)

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Ropinirole treatment (**called dopamine agonist withdrawal syndrome or DAWS**). If the problems persist more than a few weeks, **your doctor may need to adjust your dose**.

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, or aggressive behaviours. Your doctormay need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing episodes of overactivity, elation or irritability (symptoms of mania). These may occur with or without the symptoms of impulse control disorders (see above). Your doctor may need to adjust or stop your dose.

Talk to your doctor if any of these may apply to you. If you and your doctor decide that you can take ROPINIROLE, your doctor will probably ask you to have extra check-ups while you are taking it.

Other medicines and ROPINIROLE
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any herbal medicines or other medicines you obtained without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking ROPINIROLE.

Some medicines can affect the way ROPINIROLE works, or make it more likely that you will have side effects. ROPINIROLE can also affect how some other medicines work. These medicines include:

- the **anti-depressant fluvoxamine**
- medication for other **mental health problems**, for example **sulpiride**
- **metoclopramide**, which is used to treat **nausea** and **heartburn**
- **HRT** (hormone replacement therapy)
- the **antibiotics ciprofloxacin or enoxacin**.
- any other drug, which blocks dopamine in the brain.
- any other **medicine for Parkinson's disease**.
- **Tell your doctor** if you are taking, or have recently taken, any of these.

You will require additional blood tests if you are taking these medicines with ROPINIROLE:
Vitamin K antagonists (used to reduce blood clotting) such as Warfarin (coumadin).

Taking ROPINIROLE with food and drink
If you take this medicine with food, you may be less likely to feel sick (nauseous) or be sick (vomit). So it may be best to take it with food if you can.

Pregnancy and breast-feeding
ROPINIROLE is not recommended if you are pregnant, unless your doctor advises that the benefit to you of taking it is greater than the risk to your unborn baby.

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

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 ROPINIROLE.

While you are taking ROPINIROLE
Tell your doctor if you or your family notices that you are developing any **unusual behaviours** (such as an **unusual urge to gamble** or **increased sexual urges and/or behaviours**) while you are taking ROPINIROLE. Your doctor may need to adjust or stop your dose.

Driving and using machines
ROPINIROLE can make you feel drowsy. In very rare cases, ROPINIROLE **can make people feel extremely sleepy**, and it sometimes makes people fall asleep very suddenly without warning.

Ropinirole can cause hallucinations (seeing, hearing or feeling things that are not there). If affected do not drive or use machines.

If you could be affected: **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. Do not take part in these activities until you are no longer affected.
Talk to your doctor if this causes problems for you.

Smoking and ROPINIROLE
Tell your doctor if you start smoking, or give up smoking, while you are taking ROPINIROLE. Your doctor may need to adjust your dose.

If your symptoms get worse
Some people taking ROPINIROLE find that their RLS symptoms get worse - for example, symptoms may start earlier than usual or be more intense, or affect other previously unaffected limbs, such as the arms or return in the early morning.**Tell your doctor as soon as possible** if you get any of these symptoms.

ROPINIROLE contains lactose
This medicinal product contains lactose. If you have an intolerance to lactose or any other sugars, ask contact your doctor before taking this medicine.

ROPINIROLE contains sodium
Ropinirole tablets contain less than 1mmol sodium (23 mg) per tablet, that is to say essentially “sodium free”.

3. HOW TO TAKE ROPINIROLE

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

ROPINIROLE is used differently depending on the disease.

Parkinson's disease
You may be given ROPINIROLE on its own to treat the symptoms of your Parkinson's disease, or you may be given ROPINIROLE as well as another medicine called L-dopa (also called levodopa).

How much ROPINIROLE will you need to take?
It may take a while to find out the best dose of ROPINIROLE for you.

The usual starting dose is 0.25 mg of ropinirole three times each day for the first week. Then your doctor will increase your dose each week, for the next three weeks.
After that, your doctor will gradually increase the dose until you are taking the dose that is best for you. The usual is 1 mg to 3 mg three times each day (making a total daily dose of 3 mg to 9 mg). If your Parkinson's disease symptoms have not improved enough, your doctor may decide to gradually increase your dose some more. Some people take up to 8 mg of ROPINIROLE three times a day (24 mg daily altogether).

If you are also taking other medicines for Parkinson's disease, your doctor may advise you to gradually reduce the dose of the other medicine. If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you first start taking Ropinirole. Tell your doctor if this happens, as your doctor may need to adjust the dose of the medicines you are taking.

Restless Legs Syndrome

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

How much ROPINIROLE will you need to take?
It may take a while to find out what is the best dose of ROPINIROLE for you.

The usual starting dose is 0.25 mg once a day. After two days, your doctor will probably increase your dose to 0.5 mg daily for the rest of the week. Then your doctor may gradually increase your dose over the next three weeks up to a daily dose of 2 mg.

If a 2 mg daily dose does not improve your RLS symptoms enough, your doctor may gradually increase your dose some more, up to a maximum of 4 mg daily. After you have been taking ROPINIROLE for three months, your doctor may adjust your dose or advise you to stop taking it.

If you feel that the effects of ROPINIROLE are too strong or too weak, talk to your doctor or your pharmacist. **Do not take more ROPINIROLE than your doctor has recommended**.

Carry on taking this medicine as your doctor advises, even if you do not feel better. ROPINIROLE may take a few weeks to work for you.

Swallow the ROPINIROLE tablet(s) whole with a glass of water. Do not chew or crush the tablet(s).

You can take ROPINIROLE with or without food. If you take ROPINIROLE with food you may be less likely to feel sick (nauseous).

Parkinson's disease
Take ROPINIROLE 3 times a day.

Restless Legs Syndrome
Take your ROPINIROLE tablet(s) once a day.
ROPINIROLE is usually taken just before bedtime, but can be taken up to 3 hours before going to bed.

Use in children and adolescents
ROPINIROLE is not normally prescribed in children and adolescents under 18 years of age.

Do not take any more ROPINIROLE than your doctor has recommended
It may take a few weeks for Ropinirole to work for you.

If you take more ROPINIROLE than you should

Contact a doctor or pharmacist immediately. If possible show them the ROPINIROLE pack.

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

If you forget to take ROPINIROLE
Do not take extra tablets or a double dose to make up for a missed dose. Just take your next dose at the usual time.

Parkinson's disease: **If you have missed taking ROPINIROLE for one day or more**, ask your doctor for advice on how to start taking ROPINIROLE again.

Restless Legs Syndrome: **If you have missed your dose for more than a few days**, ask your doctor for advice on how to start taking ROPINIROLE again.

If you stop taking ROPINIROLE
Do not stop using ropinirole without advice.
Take ROPINIROLE for as long as your doctor recommends. Do not stop unless your doctor advises you to.
If you suddenly stop taking ROPINIROLE your Parkinson's disease symptoms may quickly get much worse.
A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include: akinesia (loss of muscle movement), rigid muscles, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, depressed level of consciousness (e.g. coma).

If you need to stop taking Ropinirole your doctor will reduce your dose gradually.
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 everyone gets them.

The side effects with this medicine are more likely to happen when you first start taking it, or when your dose has just been increased. They are usually mild and may become less troublesome after you have taken the dose for a while.

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

Parkinson's disease
When ROPINIROLE is used to treat Parkinson's disease, the following side effects have been reported:

Very common: may affect more than 1 in 10 people
- feeling sick (nausea)
- feeling drowsy

- fainting

Common: may affect up to 1 in 10 people
- hallucinations (seeing things that are not real)
- feeling dizzy (a spinning sensation)
- being sick (vomiting)
- heartburn
- swelling of the legs, , feet or hands

Uncommon: may affect up to 1 in 100 people
- feeling dizzy or faint, especially when you stand up suddenly (this is caused by a drop in blood pressure)
- Low blood pressure (hypotension)
- feeling very sleepy during the day (extreme somnolence)
- 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)
- hiccups

Some patients may have the following side effects (frequency not known: cannot be estimated from the available data)
- 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 (see Section 2)
- aggression
- excessive use of Ropinirole (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome).
- Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Ropinirole treatment.
- Changes in liver function, which have shown up in blood tests.
- spontaneous penile erection

You may experience the following side effects:
- inability to resist the impulse, drive or temptation 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 is needed to satisfy your hunger).
- episodes of overactivity, elation or irritability.

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

If you are taking this medicine with L-dopa
People who are taking this medicine with L-dopa may develop other side effects over time:

- Uncontrollable movements (dyskinesias) are a very common side effect. If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you first start taking ROPINIROLE. 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

Restless legs Syndrome
When ROPINIROLE is used to treat Restless Legs Syndrome, the following effects have been reported:

If you get any side effects, talk to your doctor or pharmacist as soon as possible. This includes any side effects not listed in this leaflet.

Very common: may affect more than 1 in 10 people
- feeling sick (nausea)
- being sick (vomiting)

Common: may affect up to 1 in 10 people
- nervousness
- fainting
- drowsiness
- fatigue (mental or physical tiredness)
- dizziness (a "spinning" sensation)
- stomach pain
- worsening of RLS (symptoms may start earlier than usual or be more intense, or affect other previously unaffected limbs, such as the arms or return in the early morning)
- swelling of the legs, , feet or hands.

Uncommon: may affect up to 1 in 100 people
- confusion
- hallucinations ('seeing' things that are not really there)
- feeling dizzy or fainting, especially when you stand up suddenly (this is caused by a drop in blood pressure).
- hiccups

Very rare: may affect up to 1 in 10,000 people
- changes in liver function, which have shown up in blood tests
- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes).

Some patients may have the following side effects (frequency not known; cannot be estimated from the available data):
- 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 (see section 2)
- other psychotic reactions in addition to hallucinations, such as severe confusion (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- aggression
- excessive use of ropinirole (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome)
- After stopping or reducing your ROPINIROLE treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).
- spontaneous penile erection

You may experience the following side effects:
- inability to resist that impulse, drive or temptation 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 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.

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; website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 ROPINIROLE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister/bottle and the outer carton after Exp. The expiry date refers to the last day of that month.

Do not store above 30°C.

Blisters:
Store in the original package in order to protect from moisture.

Bottles:
Keep the bottle tightly closed in order to protect from moisture.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ROPINIROLE contains

- The active substance is ropinirole. Each film-coated tablet contains ropinirole hydrochloride equivalent to 0.25 / 0.5 / 1.0/2.0 mg of ropinirole.

The other ingredients are:

Tablet Cores
Lactose, Anhydrous
Lactose Monohydrate
Cellulose, microcrystalline (E460)
Citric acid, anhydrous (E330)
Croscarmellose sodium (E468)
Magnesium Stearate (E572)

Film Coating

0.25 mg	Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Talc (E553b)
0.50 mg	Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Talc (E553b), Iron oxide yellow (E172), Indigo carmine aluminium lake (E132), Iron oxide

	red (E172)
1.0 mg	Hypromellose (E464), Titanium dioxide(E171), Macrogol 400, Talc (E553b), Iron oxide yellow (E172), Indigo carmine aluminium lake (E132), Iron oxide black (E172)
2.0 mg	Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Talc, Iron oxide red (E172)

What ROPINIROLE looks like and contents of the pack

Film-coated tablet.
0.25 mg: White to off-white, circular, bevelled edged, biconvex film coated tablets with '253' debossed on one side and 'G' on the other side.

0.50 mg Pale Yellow to Yellow, circular, bevelled edged, biconvex film coated tablets with '254' debossed on one side and 'G' on the other side.

1.0 mg Pale Green to Green, circular, bevelled edged, biconvex film coated tablets with '255' debossed on one side and 'G' on the other side.

2.0 mg Pale Pink to Pink, circular, bevelled edged, biconvex film coated tablets with '256' debossed on one side and 'G' on the other side.

The tablets are packed in either plain Aluminium/Aluminium blisters, white, opaque Triplex(PVC/PE/Aclar)/Aluminium blisters or white opaque HDPE bottles with polypropylene child-resistant closure.

Pack sizes
0.25 mg film-coated tablets:
Blister: 12, 21, 84 and 126
Bottle: 84

0.5 mg film-coated tablets
Blister: 21, 28 and 84
Bottle: 84

1.0 mg film-coated tablets
Blister: 21, 28 and 84
Bottle: 84

2.0 mg film-coated tablets
Blister: 21, 28 and 84
Bottle: 84

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Ltd,
Laxmi House, 2-B Draycott Avenue,
Kenton, Harrow, Middlesex HA3 0BU
United Kingdom.

Manufacturer

Glenmark Pharmaceuticals s.r.o Fibichova 143, 56617 Vysoké Mýto, Czech Republic

Glenmark Pharmaceuticals Europe Limited, Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire, WD18 8YA, United Kingdom

This leaflet was last revised in 05/2026.