

PACKAGE LEAFLET: INFORMATION FOR THE USER

ROPINIROLE 5 mg 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 5 mg film-coated tablets 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.

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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ROPINIROLE

Do not take ROPINIROLE

- if you are **allergic** to ropinirole, or any of the other ingredients of this medicine (listed in 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.

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 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. Your doctor may 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.

Tell your doctor if you think any of these may apply to you. Your doctor may decide that ROPINIROLE isn't suitable for you or that you need extra check-ups while you're taking it.

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.

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.

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.

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

- the **anti-depressant fluvoxamine**
- **HRT** (hormone replacement therapy)
- **metoclopramide**, which is used to treat **nausea** and **heartburn**
- the **antibiotics ciprofloxacin** or **enoxacin**
- any other **medicine for Parkinson's disease**

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

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)

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's 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 taking ROPINIROLE 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.

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

Driving and using machines

ROPINIROLE can make you feel drowsy. **It 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.

Important information about some of the ingredients in ROPINIROLE

ROPINIROLE tablets contains a small amount of 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 ROPINIROLE.

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

ROPINIROLE contains lactose

This medicinal product contains lactose. If you have an intolerance to lactose or any other sugars, ask your doctor for advice before you take this medicine.

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.

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).

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 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 dose 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 doses of the medicines you are taking.

Do not take any more ROPINIROLE than your doctor has recommended.

It may take a few weeks for ROPINIROLE to work for you.

Taking your dose of ROPINIROLE

Take ROPINIROLE three times a day.

Swallow the ROPINIROLE tablet(s) whole with a glass of water. It is best to take ROPINIROLE with food, because that makes it less likely that you will feel sick (nauseous).

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) or 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.

If you have missed taking ROPINIROLE for one day or more, ask your doctor for advice on how to start taking ROPINIROLE again.

If you stop taking ROPINIROLE

Do not stop taking 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 of ROPINIROLE 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.

Very common: may affect more than 1 in 10 people

- fainting
- feeling drowsy
- feeling sick (nausea)

Common: may affect up to 1 in 10 people

- hallucinations (seeing things that are not really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- 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 ROPINIROLE with L-dopa

People who are taking ROPINIROLE 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 5 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

5 mg	Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Talc, Indigo carmine aluminium lake (E132), Brilliant blue FCF Aluminium lake (E133)
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What ROPINIROLE looks like and contents of the pack

Film-coated tablet.

5 mg Blue, circular, bevelled edged, biconvex film coated tablets with '259' 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

Blister: 21 and 84

Bottle: 84

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in 06/2023.