

Ropinirole 0.25 mg film-coated tablets
Ropinirole 0.5 mg film-coated tablets
Ropinirole 2 mg film-coated tablets
ropinirole

Package leaflet:
Information for the patient

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 substance in Ropinirole 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
- the symptoms of moderate to severe restless legs syndrome.

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.

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

- Ropinirole 0.25 mg film-coated tablets: if you are allergic to ropinirole or any of the other ingredients of this medicine (listed in section 6).
- Ropinirole 0.5/2 mg film-coated tablets: if you are allergic to ropinirole, soya or peanut or to 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

Talk to your doctor or pharmacist before taking Ropinirole

- 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 **serious** mental health problem.
- if you have experienced any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour).
- if you 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 treatment.

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 is not suitable for you, or that you need extra check-ups while you are taking it.

If your restless legs 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.

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.

Children

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

Other medicines and Ropinirole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Remember to tell your doctor if you start taking any other 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 the way some other medicines work.

These include:

- the anti-depressant fluvoxamine
- HRT (hormone replacement therapy)
- the antibiotics 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
- any other medicine for Parkinson's disease
- any other drug which blocks the action of dopamine in the brain

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).

Ropinirole with food and drink

If you take Ropinirole with food, you may be less likely to feel sick (nauseous) or be sick (vomit). So it is best to take it with food if you can.

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.

Your doctor may advise you to stop taking ropinirole.

Ropinirole is not recommended if you are pregnant, unless your doctor advises that the benefit to you of 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.

Your doctor will advise you if you are breast-feeding or planning to do so.

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.

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.

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

Ropinirole contains lactose

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

Ropinirole contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated 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.

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

Ropinirole is used differently depending on the disease.

For doses not possible with this medicinal product other strengths of this medicinal product are available.

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).

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.

How much Ropinirole will you need to take?

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

The recommended 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 recommended 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.

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 tablets 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).

Restless legs syndrome

How much Ropinirole will you need to take?

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

The recommended 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 pharmacist. Do not take more Ropinirole than your doctor has recommended.

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

Taking your dose of Ropinirole

Take Ropinirole once a day.

Swallow the Ropinirole tablets 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 it with food, you may be less likely to feel sick (nauseous).

Ropinirole is usually taken just before bedtime, but you can take it up to 3 hours before you go to bed.

Elderly

Ropinirole dose should be individually titrated in patients over 65 years old, with careful monitoring of tolerability, to the optimal clinical response.

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, hallucinations.

If you forget to take Ropinirole

Do not take extra tablets or a double dose to make up for a forgotten 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 it again.

Restless legs syndrome: If you have missed taking Ropinirole for more than a few days, ask your doctor for advice on how to start taking it 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 everybody 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.

Stop taking Ropinirole and tell your doctor immediately or go to the casualty department at your nearest hospital, if the following happens:

- 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).

These are very serious side effects with unknown frequency. You may need urgent medical attention or hospitalisation.

You may experience the following side effects

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

- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - o strong impulse to gamble excessively despite serious personal or family consequences.
 - o altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
 - o uncontrollable excessive shopping or spending
 - o 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)
- 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)
- aggression
- episodes of overactivity, elation or irritability
- 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

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

Parkinson's disease

Following side effects have been reported, when ropinirole is used to treat Parkinson's disease:

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 real)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- swelling of the legs, feet and 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

Not known: frequency cannot be estimated from the available data

- changes in liver function, which have shown up in blood tests.
- Spontaneous penile erection

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 (dyskinesia) 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:

The following side effects have been reported, when ropinirole is used to treat restless legs syndrome:

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)

Uncommon: may affect up to 1 in 100 people

- confusion
- hallucinations ('seeing' things that are not really there)
- feeling dizzy or faint, 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

- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- changes in liver function which have shown up in blood tests.

Not known: frequency cannot be estimated from the available data

Some patients may have the following side effects

- other psychotic reactions in addition to hallucinations, such as severe confusion (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- spontaneous penile erection

Ropinirole 0.5/2 mg film-coated tablets: lecithin (soya) may cause very rarely allergic reactions.

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 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 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 foil and carton after EXP. The expiry date refers to the last day of that month

Ropinirole 0.25 mg: Do not store above 25°C. Store in the original container.

Ropinirole 0.5 mg: Do not store above 25°C. Store in the original container.

Ropinirole 2 mg: Do not store above 30°C. Store in the original container.

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 Ropinirole contains

The active substance is ropinirole hydrochloride.

- Each Ropinirole 0.25 mg film-coated tablet contains 0.285 mg ropinirole hydrochloride, equivalent to 0.25 mg ropinirole.
- Each Ropinirole 0.5 mg film-coated tablet contains 0.57 mg ropinirole hydrochloride, equivalent to 0.5 mg ropinirole.
- Each Ropinirole 2 mg film-coated tablet contains 2.28 mg ropinirole hydrochloride, equivalent to 2 mg ropinirole.

The other ingredients are lactose monohydrate, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium and magnesium stearate.

The tablet coating contains:

- Ropinirole 0.25 mg (Opadry II 85F18422): poly (vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350 and talc.
- Ropinirole 0.5 mg (Opadry II 85G32558): poly(vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, lecithin (soya) (E322), iron oxide yellow (E172) and iron oxide black (E172).
- Ropinirole 2 mg (Opadry II 85G34363): poly(vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, lecithin (soya) (E322), carmine (E120), iron oxide yellow (E172) and iron oxide black (E172).

What Ropinirole looks like and contents of the pack

Ropinirole 0.25 mg is a white, round slightly arched film-coated tablet, debossed "R 0.25" on one side and plain on the other.

Ropinirole 0.5 mg is a yellow, round slightly arched film-coated tablet, debossed "R 0.5" on one side and plain on the other.

Ropinirole 2 mg is a pink, round slightly arched film-coated tablet, debossed "R 2" on one side and plain on the other.

Ropinirole 0.25 mg is available in pack sizes of 12, 15, 21, 24, 30, 60, 81, 84, 90, 100, 126, 210 and 50 unit dose blisters (hospital presentation pack).

Ropinirole 0.5 mg is available in pack sizes of 15, 21, 28, 30, 60, 84, 90, 100 and 126.

Ropinirole 2 mg is available in pack sizes of 15, 21, 28, 30, 60, 84, 90 and 100 and 50 unit dose blisters (hospital pack).

Not all pack sizes may be marketed.

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