

Ropinirole 0.25 mg Film-coated Tablets Ropinirole 0.5 mg Film-coated Tablets Ropinirole 1 mg Film-coated Tablets Ropinirole 2 mg Film-coated Tablets Ropinirole (as hydrochloride)

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.

What is in this leaflet

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1. What Ropinirole Film-coated Tablets are and what they are used for

Ropinirole belongs to a group of medicines called dopamine agonists. Dopamine agonists act like a naturally occurring chemical in your brain called dopamine.

Ropinirole Film-coated Tablets are used to treat the symptoms of moderate to severe idiopathic Restless Legs Syndrome.

Moderate to severe Restless Legs Syndrome is typically represented by patients who have difficulty sleeping or severe discomfort in their legs or arms. It is a condition characterised by an irresistible urge to move the legs and occasionally the arms, usually accompanied by uncomfortable sensations such as tingling, burning or prickling. These feelings occur during periods of rest or inactivity such as sitting or lying down, especially in bed, and are worse in the evening or at night. Usually the only relief is obtained by walking about or moving the affected limbs, which often leads to problems sleeping. Ropinirole Film-coated Tablets relieve the discomfort and reduce the urge to move the limbs that disrupts night time sleep.

Ropinirole is also authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

2. What you need to know before you take Ropinirole Film-coated Tablets

Do not take Ropinirole Film-coated Tablets:

- if you are allergic to ropinirole or any of the other ingredients of this medicine (listed in section 6).
- if you have serious liver disease.
- if you have serious kidney disease.

If you are unsure, it is essential to talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ropinirole Film-coated Tablets if you:

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

In these situations your doctor should carefully supervise your treatment.

During treatment with Ropinirole Film-coated Tablets take special care when you drive or operate machinery. If you suffer from extreme sleepiness or suddenly fall asleep without apparently feeling sleepy, do not drive or use machinery, and contact your doctor.

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.

During treatment for Restless Legs Syndrome: If your symptoms become worse, start earlier in the day or after less time at rest, or affect other parts of your body such as your arms, you should see your doctor who may adjust the dose of ropinirole that you are taking.

Children and adolescents

Ropinirole Film-coated Tablets are not recommended for use in children and adolescents.

Taking other medicines and Ropinirole Film-coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This applies also to herbal medicines as well as strong vitamins and minerals.

The effect of Ropinirole Film-coated Tablets may be increased or decreased by other medicines, and vice versa. These medicines include:

- ciprofloxacin (an antibiotic)
- enoxacin (an antibiotic)
- fluvoxamine (a drug used to treat depression)
- theophylline (a drug used to treat asthma)
- hormone replacement therapy (also called HRT)
- anti-psychotics and other drugs that block dopamine in the brain (e.g. sulpiride or metoclopramide)

Tell your doctor if:

- you are taking medicines to treat high blood pressure, or for heart problems
- you give up or start smoking while taking Ropinirole Film-coated Tablets. Your doctor may need to adjust your dose.
- you are taking Ropinirole Film-coated Tablets and the doctor is going to prescribe you any other medicine.

Ropinirole Film-coated Tablets with food, drink and alcohol

Always swallow the tablets whole with water and preferably with food. Do not chew them.

Taking Ropinirole Film-coated Tablets with food may reduce the likelihood of you feeling or being sick.

You should not drink alcohol while you are taking 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 for advice before taking this medicine.

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.

Your doctor will advise you if you are breast feeding or planning to do so. Your doctor may advise you to stop taking Ropinirole.

Driving and using machines

This medicine does not usually affect people's normal activities. However, Ropinirole Film-coated Tablets can cause extreme sleepiness (somnolence) in some people and may cause them to fall asleep suddenly without any apparent warning. Contact your doctor if you experience either of these effects. If you do suffer from these effects then DO NOT drive or operate machinery, and do not put yourself in any situation where sleepiness or falling asleep may put you (or others) at risk of serious injury or death.

Ropinirole Film-coated Tablets contain lactose

Patients who are intolerant to lactose should note that each Ropinirole Film-coated Tablet contains a small amount of 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.

3. How to take Ropinirole Film-coated Tablets

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

Swallow the Ropinirole Film-coated Tablet(s) whole with water. You can take the tablets with or without food. However, taking Ropinirole Film-coated Tablets with food may decrease the occurrence of nausea (feeling sick) which is a possible side-effect of the tablets. Do not chew the tablet(s). Do not take more than your doctor has recommended.

When you first start taking Ropinirole Film-coated Tablets, the amount you take will be increased gradually.

The exact dose of ropinirole that people take can be different. Your doctor will decide on the dose you need to take each day and you should follow the doctor's instructions.

When treating Restless Legs Syndrome, Ropinirole Film-coated Tablets should be taken once a day, at about the same time each day. They are usually taken just before bedtime, but can be taken up to 3 hours before going to bed.

The starting dose is 0.25 mg once daily. After two days your doctor will probably increase your dose to 0.5 mg once daily for the remainder of your first week of treatment. Your doctor may then increase your dose by 0.5 mg per week over three weeks to a dose of 2 mg per day. In some patients with insufficient improvement, the dose may be increased gradually up to a maximum of 4 mg daily.

After three months of treatment with Ropinirole Film-coated Tablets, your doctor may adjust your dose or discontinue your treatment depending on your symptoms and how you feel.

Please read the pharmacist's label carefully. If you have any questions about Ropinirole Film-coated Tablets and how to take them, ask your doctor or pharmacist.

If you take more Ropinirole Film-coated Tablets than you should

You should never take more tablets than your doctor recommends. Someone who has taken an overdose may experience; feeling or being sick, dizziness (or a spinning sensation), feeling drowsy, fatigue (mental or physical tiredness), stomach pain, fainting or nervousness. If you take too many tablets, or if someone else has taken your medicine, tell a doctor or pharmacist straight away. Show them your pack of tablets.

If you forget to take Ropinirole Film-coated Tablets

Remember to take your medicine. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you do forget to take a dose, leave out that dose completely. Take your next dose at the normal time.

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

If you have missed taking your tablets for more than a few days, consult your doctor for advice on restarting.

If you stop taking Ropinirole Film-coated Tablets

You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to start to work. If you have the impression that the effect of your medicine is too strong or too weak, talk to your doctor or pharmacist.

If you wish to stop the treatment, this has to be done gradually. You must not stop taking Ropinirole Film-coated Tablets without your doctor's advice. If your symptoms worsen after you stop treatment with Ropinirole Film-coated Tablets, you should contact your doctor.

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 more common side effects of Ropinirole Film-coated Tablets sometimes occur when patients first start their therapy and/or when the dose is increased. The side effects are generally mild and may become less after you have taken the medicine for a short time.

Restless Legs Syndrome

The side effects reported in people taking ropinirole for Restless Legs Syndrome are listed below:

Very Common Side Effects (they occur in more than 1 per 10 patients who receive treatment)

Vomiting, nausea (feeling sick)

Common Side Effects (they occur in between 1 and 10 per 100 patients who receive treatment)

Nervousness, fainting, drowsiness, dizziness (or a spinning sensation), stomach ache, fatigue (mental or physical tiredness)

Uncommon Side Effects (they occur in between one and ten per 1000 patients who receive treatment)

Confusion, hallucinations, low blood pressure which may make you feel dizzy or faint especially when standing up from a sitting or lying position

Very rare (they occur in less than one per 10,000 patients who receive treatment)

Hepatic reactions (mainly increase of liver enzymes), extreme sleepiness or sudden sleep onset episodes (suddenly falling asleep without any apparent warning)

Unknown (frequency cannot be estimated from the data)

Dopamine Dysregulation Syndrome (DDS) (craving dopaminergic medication, euphoric feelings after taking medicine, compulsive behavior)

Some patients may have the following side effects

- 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)

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 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.

During treatment with Ropinirole Film-coated Tablets you may experience unusual worsening of symptoms (e.g. symptoms become worse, start earlier in the day or after less time at rest, or affect other parts of your body such as your arms). If this occurs, you should see your doctor.

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropinirole Film-coated Tablets

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

Do not store above 25°C.

Store in the original package in order to protect from light. HDPE containers only: Keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister foil.

The expiry date refers to the last day of that month.

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 Film-coated Tablets contain

The active substance is ropinirole (as ropinirole hydrochloride).

The other ingredients are:

Tablet Core

- Lactose Monohydrate
- Microcrystalline cellulose
- Pregelatinised starch
- Magnesium stearate

Film Coating

0.25 mg: Opadry II 85F18378 (Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc)

0.5 mg: Opadry II 85F32111 (Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide yellow (E172))

1 mg: Opadry II 85F21676 (Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide yellow (E172), Brilliant blue aluminium lake (E133), Iron oxide black (E172))

2 mg: Opadry II 85F24026 (Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide yellow (E172), Iron oxide red (E172))

What Ropinirole Film-coated Tablets look like and contents of the pack

The **0.25 mg** film-coated tablets are white, round, biconvex and 7 mm in diameter.

They are marked R0.25 on one side.

The **0.5 mg** film-coated tablets are yellow, round, biconvex and 7 mm in diameter.

They are marked R0.5 on one side.

The **1 mg** film-coated tablets are green, round, biconvex and 7 mm in diameter.

They are marked R1 on one side.

The **2 mg** film-coated tablets are pink, round, biconvex and 7 mm in diameter.

They are marked R2 on one side.

Pack sizes:

Ropinirole film-coated tablets are available in blister packs of 12, 28 or 84 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer:

Actavis Ltd
B16 Bulebel Industrial Estate
Zejtun ZTN08
Malta

This leaflet was last revised in August 2015