

Package leaflet: Information for the user

Invented name 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, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What is Ropinirole Accord and what it is used for

The active substance in Ropinirole Accord 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 dopamine.

Ropinirole Accord is used to treat Parkinson's disease.

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

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

Patients with moderate to severe Restless Legs Syndrome generally complain of trouble sleeping or severe discomfort in the legs or arms.

Patients with Restless Legs Syndrome have an irresistible urge to move their legs, and sometimes their arms and other parts of their body. They usually have an uncomfortable feeling in the legs (sometimes described as pins and needles, burning sensation) which occurs when resting or during periods of inactivity, when sitting or lying down (particularly when sleeping) and worsens in the evening or at night. Walking or moving the affected limbs is usually the only relief, which often affects sleeping.

Ropinirole Accord relieves discomfort sensations and so reduces the urge to move the legs or other limbs.

2. What you need to know before you take Ropinirole Accord

If your doctor has told you that you have a sugar intolerance, speak to him/her before taking this medicine.

Do not take Ropinirole Accord

- If you are allergic (hypersensitive) to ropinirole, 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, pharmacist or nurse before taking Ropinirole Accord:

Your doctor needs to know before you take Ropinirole Accord

- If you are pregnant or think you might be pregnant.
- If you are breast-feeding
- If you are under 18 years old
- If you have serious heart complaint
- If you have serious mental health problem
- if you have an intolerance to some sugars (such as lactose)

Tell your doctor if you think any of these may apply to you. Your doctor may decide that Ropinirole Accord isn't suitable for you, or that you need extra check-ups while you are 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.

While you are taking Ropinirole Accord:

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 Accord. Your doctor may need to adjust or stop your dose.

Driving and using machines

Ropinirole Accord 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.

Smoking and Ropinirole Accord

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

Other medicines and Ropinirole Accord:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Ropinirole Accord.

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

- the anti-depressant fluvoxamine,
- medication for other mental health problems, for example sulpiride
- 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.

Taking Ropinirole Accord with food and drink

If you take Ropinirole Accord 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, breast-feeding and fertility

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

Important information about some of the ingredients in Ropinirole Accord

This medicinal product contains 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 this medicinal product.

3. How to take Ropinirole Accord

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

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

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

How much Ropinirole Accord will you need to take?

Parkinson's disease

It may take a while to find out the best dose of Ropinirole Accord 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 Accord 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 Accord. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.

Restless Legs Syndrome

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

The initial dose is 0.25 mg once a day. After two days, your doctor will probably increase the dose to 0.5 mg once a day up to the end of your first week of treatment. Your doctor could then increase your dose by 0.5 mg a week for 3 weeks up to 2 mg a day.

If the improvement in your symptoms is insufficient with the 2 mg a day dose, your doctor could gradually increase the dose up to a maximum of 4 mg per day. After 3 months of Ropinirole Accord treatment, depending on your symptoms and your general health, your doctor will adapt your dose or discontinue your treatment.

If you feel that the effects of Ropinirole Accord are too strong or too weak, talk to your doctor or your pharmacist. Do not take a higher dose than prescribed.

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

Do not take any more Ropinirole Accord than your doctor has recommended.

It may take a few weeks for Ropinirole Accord to work for you.

Taking your dose of Ropinirole Accord

Take Ropinirole Accord three times a day.

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

If you take more Ropinirole Accord than you should:

Contact a doctor or pharmacist immediately. If possible, show them the Ropinirole Accord pack. Someone who has taken an overdose of Ropinirole Accord 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 Accord:

Do not 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 Ropinirole Accord for one day or more, ask your doctor for advice on how to start taking it again.

If you stop taking Ropinirole Accord

Take Ropinirole Accord for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking Ropinirole Accord, your disease symptoms may quickly get much worse. If you need to stop taking Ropinirole Accord, your doctor will reduce your dose gradually.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of Ropinirole Accord can occur in patients who take this treatment for the first time and/or when the dose is increased. These side effects are generally mild and can spontaneously ease after taking this medicine for a few days. Tell your doctor if you experience any side effects that worry you.

Very common side effects (affects more than 1 in 10 people)

- fainting
- feeling drowsy
- feeling sick (nausea)

Common side effects (affects up to 1 in 10 people)

- hallucinations (seeing things that aren't really there),

- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- swelling of the legs
- fatigue (mental or physical)
- being sick (vomiting)
- nervousness.

Uncommon side effects (affects 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)
- 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)

Very rare side effects:

A small number of people taking Ropinirole Accord (up to 1 in 10,000) have experienced a change in liver function (increased enzymes) detected in a blood test.

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).

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 behaviors; they will discuss ways of managing or reducing the symptoms

If you take Ropinirole Accord in combination with levodopa (L-dopa):

In patients combining Ropinirole Accord and L-dopa, other side effects can occur 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 Accord. 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 you experience side effects:

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

5. How to store Ropinirole Accord

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

Do not store above 25°C.

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 Accord contains

- The active substance is Ropinirole. Each Ropinirole Accord tablet contains either 0.25 mg, 0.5 mg, 1 mg or 2 mg of the active substance (as ropinirole hydrochloride). The exact amount is shown on your Ropinirole Accord tablet pack.
- The other ingredients are
 - (tablet core) cellulose microcrystalline, lactose monohydrate, sodium croscarmellose, magnesium stearate and

In addition the different Ropinirole Accord tablet strengths also contain the following ingredients:

TABLET STRENGTH	OTHER INGREDIENTS
0.25 mg	(tablet coating) OPADRY white (13B58802): hypromellose, titanium dioxide (E171), macrogol 400, polysorbate 80
0.5 mg	(tablet coating) OPADRY yellow (03B82930): hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), indigo carmine aluminium lake (E132), iron oxide red (E172)
1mg	(tablet coating) OPADRY green (03B51430): hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), indigo carmine aluminium lake (E132)
2mg	(tablet coating) OPADRY pink (03B54094): hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), iron oxide red (E172).

What Ropinirole Accord looks like and contents of the pack

Ropinirole Accord 0.25 mg is a film-coated tablet, round biconvex, plain on both sides, white to off-white.

Ropinirole Accord 0.5 mg is a film-coated tablet, round biconvex, plain on both sides, yellow.

Ropinirole Accord 1 mg is a film-coated tablet, round biconvex, plain on both sides, green.

Ropinirole Accord 2 mg is a film-coated tablet, round biconvex, plain on both sides, pink.

Ropinirole Tablets are packed in Alu-Alu blisters

Each blister strip contains 7 tablets, pack-sizes of 21 or 42 tablets (For 0.25mg, 0.5mg and 1mg strength) and pack-sizes of 21 or 63 tablets (For 2mg strength)

Ropinirole Tablets are also packed in HDPE bottles with PPCTC closure. Each bottle contains 21 or 84 tablets and a silica gel canister.

Not all pack sizes or pack type may be marketed.

Marketing Authorisation Holder and Manufacturer

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Marketing Authorisation Number

0.25mg: PA 1390/052/001
0.5mg: PA 1390/052/002
1mg: PA 1390/052/003
2mg: PA 1390/052/004
5mg: PA 1390/052/005

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