

Package leaflet: Information for the user

ROPIRADE 0.25mg film-coated tablets **ROPIRADE 1mg film-coated tablets** **ROPIRADE 2mg 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 Ropirade is and what it is used for
2. What you need to know before you take Ropirade
3. How to take Ropirade
4. Possible side effects
5. How to store Ropirade
6. Contents of the pack and other information

1. What Ropirade is and what it is used for

The active ingredient in Ropirade 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.

Ropirade is used

- **to treat of 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.
- **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.
 - Ropirade 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 Ropirade

Do not take Ropirade

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

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

Warnings and precautions

Talk to your doctor before taking Ropirade:

- 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 intend to give up or start smoking because your doctor may need to adjust your dose.

Tell your doctor if you think any of these may apply to you. Your doctor may decide that Ropirade 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.

In these situations, your doctor should carefully monitor your treatment.

Restless Legs Syndrome

If during treatment 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, your doctor may adjust the dose of Ropirade that you are taking.

Children and adolescents

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

Other medicines and Ropirade

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Ropirade works, or make it more likely that you will have side effects. Ropirade can also affect the way some 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**
- ciprofloxacin (an antibiotic)
- any other drug which blocks the action of dopamine in the brain
- any other **medicine for Parkinson's disease**.

You will require additional blood tests if you are taking these medicines with Ropirade:

Vitamin K antagonists (used to reduce blood clotting) such as warfarin (Coumadin).

Taking Ropirade with food and drink

If you take Ropirade 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

Ropirade is not recommended if you are pregnant, unless your doctor advises that the benefit to you of taking Ropirade is greater than the risk to your unborn baby. **Ropirade 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 that you might be pregnant, or if you are planning to become pregnant. Your doctor will advise you if you are breast feeding or planning to do so. Your doctor may advise you to stop taking Ropirade.

Driving and using machines

Ropirade 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.

Ropirade contains 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 Ropirade

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

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

For doses not realisable/practicable with this strength other strengths of this medicinal product are available.

There are 4 strengths of Ropirade film-coated tablets available:

0.25 mg, 1 mg, 2 mg and 5 mg.

Please note the different dosages for:

a) Treatment of Parkinson's disease

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

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

b) Treatment of Restless Legs Syndrome

Take Ropirade once a day, every day at about the same time. Ropirade is usually taken just before bedtime, but can be taken up to 3 hours before going to bed. The exact dose of Ropirade 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 you begin taking Ropirade, the dose you take will be increased gradually.

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. Then your doctor may 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 Ropirade, your doctor may adjust your dose or discontinue your treatment depending on your symptoms and how you feel.

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

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

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

If you take more Ropirade than you should

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

Someone who has taken an overdose of Ropirade may have any of these symptoms:

- fainting,
- feeling drowsy,
- feeling sick (nausea),
- being sick (vomiting),
- hallucinations,
- dizziness (or spinning sensation),
- mental or physical tiredness.

If you forget to take Ropirade

Do not take an extra dose to make up for forgotten individual doses.

Just take your next dose of Ropirade at the usual time.

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

If you stop taking Ropirade

Do not stop taking Ropirade without advice.

Take Ropirade for as long as your doctor recommends.

If you need to stop taking Ropirade, 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. Tell your doctor if you notice any side effects and they worry you.

The side effects of Ropirade 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're worried about side effects, talk to your doctor.

Possible side effects in treatment of 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 aren't really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- abdominal pain
- swelling of the legs

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)
- 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)

Not known: frequency 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)
- changes in liver function, which have shown up in abnormal blood tests

If you are taking Ropirade with L-dopa

People who are taking Ropirade 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 Ropirade. 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

Possible side effects in treatment of 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)

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

- 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)

Possible side effects valid for both treatments

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.
 - Levodopa, dopamine agonist and COMT inhibitor products July 2012 Page 4/4
 - 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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. How to store Ropirade

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 or bottle label and outer carton after "EXP". The date refers to the last day of that month.

PVC/Aclar/Aluminium blister: Do not store above 25 °C. In order to protect from moisture store in the original package.

HDPE bottles: Do not store above 30 °C. In order to protect from moisture keep the bottle tightly closed.

Aluminium/Aluminium blister: Do not store above 30 °C. In order to protect from moisture store in the original package.

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 Ropirade contains:

- The active substance is ropinirole.

Ropirade 0.25 mg: One film-coated tablet contains 0.285 mg ropinirole hydrochloride equivalent to 0.25 mg ropinirole

Ropirade 1 mg: One film-coated tablet contains 1.14 mg ropinirole hydrochloride equivalent to 1.0 mg ropinirole

Ropirade 2 mg: One film-coated tablet contains 2.28 mg ropinirole hydrochloride equivalent to 2.0 mg ropinirole

- The other ingredients are:
 - Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate
 - Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171), polysorbate 80
- Ropirade 1 mg:** yellow iron oxide (E172), indigo carmine aluminium lake (E132)
- Ropirade 2 mg:** red iron oxide (E172), yellow iron oxide (E172), indigo carmine aluminium lake (E132)

What Ropirade looks like and contents of the pack

Ropirade 0.25 mg are round, white film-coated tablets.

Ropirade 0.25 mg is available in packs (blisters) of 7, 12, 21, 30, 50, 60, 84, 90, 126 or 210 film-coated tablets and in bottles with 7, 12, 21, 30, 50, 60, 84, 90, 126 or 210 (2x105) film-coated tablets.

Ropirade 1 mg are round, green film-coated tablets.

Ropirade 1 mg is available in packs (blisters) of 7, 21, 30, 50, 60, 84 or 90 film-coated tablets and in bottles with 7, 21, 30, 50, 60, 84 or 90 film-coated tablets.

Ropirade 2 mg are round, pink film-coated tablets.

Ropirade 2 mg is available in packs (blisters) of 7, 21, 30, 50, 60, 84 or 90 film-coated tablets and .in bottles with 7, 21, 30, 50, 60, 84 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Iberfar - Indústria Farmacêutica, S. A., Rua Consiglieri Pedroso, n.º 121 - 123 - Queluz de Baixo, Barcarena 2745-557, Portugal

STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Ropinirole EG
Bulgaria:	ROPINSTAD
Denmark:	Ropinirol Stada filmovertrukne tabletter
France:	ROPINIROLE EG comprimé, pelliculé
Germany:	Ropinirol STADA Filmtabletten
Hungary:	ROPINSTAD
Ireland:	Ropirade film-coated tablets
Italy:	ROPINIROLO EG compresse rivestita con film
The Netherlands:	Ropinirol CF filmomhulde tabletten
Norway:	Ropinirol Stada
Poland:	ROPINSTAD
Portugal:	Ropinirol Ciclum
Spain:	Ropinirol STADA comprimidos recubiertos con película EFG
Sweden:	Ropinirol Stada filmdragerade tabletter

This leaflet was last revised in October 2013.