PACKAGE LEAFLET

Package leaflet: Information for the patient

Ropinirole 0.25mg 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.
- 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 have any more questions, ask your doctor or pharmacist (chemist).

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 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.

Ropinirole is also 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.

Restless Legs Syndrome 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 inn 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 relieves the discomfort and reduces the urge to move the limbs that disrupts night time sleep.

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 a 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. Medicines are not always suitable for everyone. Your doctor needs to know before you take Ropinirole if you suffer from or have suffered in the past from any of the following conditions:
- you are **pregnant** or think you may be pregnant
- you are **breast feeding**
- you are **under 18** years old
- you have a **serious heart complaint**
- 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 dose.

Tell your doctor if you or your family/carer notices 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, or aggressive behaviours. 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 are 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.

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) a 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.

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. Remember to tell your doctor or pharmacist if you begin taking new 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**
- 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 or Restless Legs Syndrome.

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).

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.

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'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 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.

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.

Important Information about some of the ingredients in Ropinirole

Lactose
Ropinirole 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.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per 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 to. 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 Restless Legs Syndrome. 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.

Swallow the Ropinirole tablet(s) whole with water. Do not chew or crush the tablet(s).

The exact dose of ropinirole people take can be different. Your doctor will decide on the dose you need to take each day and you should follow the doctors instructions. When you first start taking Ropinirole, the dose you take will be increased gradually.

How much Ropinirole will you need to take?

Parkinson's disease

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.

Restless Legs Syndrome
Take Ropinirole once a day by mouth, every day at the same time each day. Ropinirole is usually taken just before bedtime, but can be taken up to 3 hours before you go to bed.

The starting dose is 0.25 mg once daily. After two days your doctor will probably increase you dose to 0.5 mg once daily for the remainder of your first week of treatment. Then your doctor may gradually increase your dose over the next three weeks to a dose of 2 mg per day.

If your symptoms have not improved, the dose may be increased gradually up to a maximum of 4 mg daily. After three months of treatment with Ropinirole, your doctor may adjust your dose or discontinue your treatment depending on your symptoms and how you feel.

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

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

If your symptoms get worse
Occasionally, people taking Ropinirole find that their Restless Legs Syndrome symptoms get worse. For example, symptoms may start earlier in the day, after a shorter time at rest, or the symptoms may affect other parts of the body, such as the arms. **See your doctor** if this happens to you.

Taking your dose of Ropinirole
Swallow your 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), being sick (vomiting), dizziness (a spinning sensation), feeling drowsy, mental or physical tiredness, fainting, seeing, feeling or hearing things that are not there (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 it again.

Do not stop taking Ropinirole without advice
Take Ropinirole for as long as your doctor recommends. Do not stop unless your doctor advises you

If you suddenly stop taking Ropinirole, your symptoms may quickly get much worse. A sudden stop could also 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're worried about side effects, talk to your doctor.

Very common side effects
These may affect more than 1 in 10 people taking Ropinirole:
- fainting (sncope)
- feeling drowsy
- feeling sick (nausea)

Common side effects
These may affect up to 1 in 10 people taking Ropinirole:
- hallucinations ('seeing' things that aren't really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- swelling of the legs, feet or hands
- **nervousness**
- **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 side effects
These may affect up to 1 in 100 people taking Ropinirole:
- low blood pressure (hypotension)
- 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)
- 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).
- after stopping or reducing ropinirole treatment: depression, apathy (indifference), anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).
- changes in your liver function, which have shown up in blood tests.
- spontaneous penile erection

You may experience the following side effects:
- inability to resist that 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 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

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

This medicine does not require any special storage conditions.

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 in Ropinirole is ropinirole.

Each film-coated tablet contains 0.25 mg, 0.5 mg, 1 mg or 2 mg ropinirole (as hydrochloride)

The other ingredients are: microcrystalline cellulose, lactose monohydrate (see section 2, “Ropinirole contains lactose”), croscarmellose sodium, hypromellose, magnesium stearate.

The coating includes:
0.25 mg: hypromellose, titanium dioxide (E171), macrogol, polysorbate

0.5 mg: hypromellose, titanium dioxide (E171), macrogol, iron oxide yellow (E172)

1mg: hypromellose, macrogol , iron oxide yellow (E172), titanium dioxide (E171), Indigo carmine (E132)

2mg: hypromellose, titanium dioxide (E171), macrogol, iron oxide red (E172), iron oxide yellow (E172)

What Ropinirole looks like and contents of the pack

Your medicine comes as a film-coated tablet.

Ropinirole 0.25 mg: White to off-white colour, capsule shaped biconvex, film-coated tablets with break-line on both sides.
Ropinirole 0.5 mg: Yellow coloured, capsule shaped biconvex, film-coated tablets with break-line on both sides.
Ropinirole 1 mg: Green coloured, capsule shaped biconvex, film-coated tablets with break-line on both sides.
Ropinirole 2 mg: Light pink, capsule shaped biconvex, film-coated tablets with break-line on both sides.

The tablet can be divided into equal halves.

Ropinirole is available in HDPE multidose container with child resistant closure (PP) of 12 (0.25 mg only), 21, 28, 84 and 126 tablets.

Not all pack sizes may be marketed.

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