Package Leaflet: Information for the user

Ropinirole 0.25mg, 0.5mg, 1mg and 2mg Film-coated Tablets

ropinirole hydrochloride

(Referred to as Ropinirole Tablets in the remainder of the leaflet)

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 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ropinirole Tablets are and what they are used for

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

3. How to take Ropinirole Tablets

4. Possible side effects

5. How to store Ropinirole Tablets

6. Contents of the pack and other information

1. What Ropinirole Tablets are and what they are used for

The active ingredient in Ropinirole 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 Tablets are 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.

• moderate to severe Restless Legs Syndrome. People with Restless Legs Syndrome have an irresistible urge to move their legs, and sometimes their arms and other parts of their body. 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 Tablets

Do not take Ropinirole Tablets:

• if you are allergic 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 or pharmacist before taking Ropinirole Tablets:
• 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 are taking medicines to treat high blood pressure
• if you are taking medicines to control your heart beat

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Ropinirole treatment. 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 you dose.

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

Children

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

Other medicines and Ropinirole Tablets

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

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

These include:

• the anti-depressant fluvoxamine

• HRT (hormone replacement therapy)

• the antibiotics ciprofloxacin or enoxacin

• medications 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

Tell your doctor if you're taking, or have recently taken any of these.
Remember to tell your doctor if you start taking any other medicine while you're taking Ropinirole Tablets.

Ropinirole Tablets with food and drink

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

Pregnancy and Breast-feeding

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

Ropinirole Tablets are not recommended if you are breast-feeding, as it can affect your milk production.

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 Tablets.

Driving and using machines

Ropinirole Tablets 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) 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 Tablets

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

If your symptoms get worse

Some people taking Ropinirole Tablets find that their Restless Leg Syndrome 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.

Ropinirole Tablets contain lactose

This medicine contains lactose (a type of sugar). 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 Tablets

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

This medicine is to be swallowed whole with water and preferably with food.

You may be given Ropinirole Tablets on its own to treat the symptoms of your Parkinson's disease, or you may be given Ropinirole Tablets 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 Tablets. Tell your doctor if this happens, as your doctor may need to adjust the dose of the medicines you are taking.

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

Treatment of Parkinson's disease:

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

The recommended dose is 0.25mg of ropinirole three times a day. 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 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 Tablets 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.

Treatment of Restless Legs Syndrome:

Adults

Take Ropinirole Tablets once a day, usually just before bedtime, but you can take it up to 3 hours before you go to bed. After two days your doctor may increase your dose to 0.5mg once a day for the remainder of the week. Then your doctor may gradually increase your dose to 2mg once a day over the next three weeks. In some patients, a 2mg daily dose may not improve Restless Legs Syndrome enough and your doctor may increase the dose up to a maximum of 4mg daily to improve your symptoms.

After three months of taking Ropinirole Tablets, your doctor may adjust your dose or advise you to stop taking this medicine, depending on your symptoms and how you feel.

If you take more Ropinirole Tablets than you should

Contact a doctor or pharmacist or go to your nearest hospital casualty department immediately. Take this leaflet and any unused tablets with you to show the doctor.

Someone who has taken an overdose of Ropinirole Tablets 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 Tablets

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 Tablets for more than a few days, ask your doctor for advice on how to start taking it again

If you stop taking Ropinirole Tablets

Do not stop taking this medicine without advice.

Take Ropinirole Tablets for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you stop taking Ropinirole Tablets 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 Tablets 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, Ropinirole Tablets can cause side effects, although not everybody gets them. The side effects of Ropinirole Tablets 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.

If you notice any of the following side effects, talk to a doctor or go to a hospital immediately:
• 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).
• low blood pressure (feeling faint, dizzy or light headed)

• after stopping or reducing your Ropinirole Tablets treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called Dopamine agonist withdrawal syndrome or DAWS).

Treatment of Parkinson's disease:

The following side effects may be experienced when taking Ropinirole Tablets:

Very common (may affect more than 1 in 10 people):

• feeling drowsy

• feeling sick (nausea)

• fainting.

Common (may affect up to 1 in 10 people):

• hallucinations (seeing or hearing things that are not there)

• feeling dizzy (a spinning sensation)

• stomach pain

• being sick (vomiting)

• heartburn

• swelling of the legs, feet or 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)

• 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).

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

Very rare (may affect up to 1 in 10,000 people):
• changes in liver function, which have shown up in blood tests
• 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.

Not known (frequency cannot be estimated from the available data)

• aggression

• excessive use of Ropinirole Tablets (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome).

If you are taking Ropinirole Tablets with L-dopa

People who are taking Ropinirole Tablets with L-dopa may develop other side effects over time:

• uncontrollable movements (dyskinesias) are a very common side effect. 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 may be experienced when taking Ropinirole Tablets:

Very common (may affect more than 1 in 10 people):

• being sick (vomiting)

• feeling sick (nausea)

Common (may affect up to 1 in 10 people):

• feeling nervous

• fainting

• feeling drowsy

• fatigue (mental or physical tiredness)

• dizziness

• stomach pain

• worsening of RLS (symptoms may start earlier than usual or be more intense, or affect other parts of the body, such as the arms or return in the early morning)

Uncommon (may affects up to 1 in 100 people):

• feeling confused

• hallucinations ('seeing' things that are not really there)

• low blood pressure which can make you feel dizzy or faint especially when standing up from a sitting down or lying position.

• feeling very sleepy during the day (extreme somnolence)

• falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes

Not known (frequency cannot be estimated from the available data)

• changes in liver function, which have shown up in blood tests

• Dopamine Dysregulation Syndrome (DDS) (craving dopaminergic medication, euphoric feelings after taking Ropinirole Tablets, compulsive behaviour).

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 <[To be completed nationally] >
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropinirole Tablets

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

Do not use this medicine after the expiry date stated on the blister or carton. The expiry date refers to the last day of that month.

For tablets packed in plastic bottles: Ropinirole Tablets can be used for one month after first opening of the container.

Blisters: Store below 25°C. Store in the original package (blister) in order to protect from moisture.
HDPE bottles: Store below 25°C. Keep the bottle tightly closed in order to protect from moisture.

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 tablets contain
The active ingredient is ropinirole hydrochloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose (6cps), magnesium stearate.

Film coating:
Ropinirole 0.25mg Film-Coated tablets: opadry white 03B28796 (hypromellose 6cps, titanium dioxide (E171), macrogol).
Ropinirole 0.5mg Film-Coated tablets: opadry yellow 03B52117 (hypromellose 6cps, titanium dioxide (E171), macrogol, iron oxide yellow (E172)).
Ropinirole 1mg Film-Coated tablets: opadry green 03B21595 (hypromellose 6cps, titanium dioxide (E171), macrogol, iron oxide yellow (E172), indigo carmine aluminium lake (E132)).
Ropinirole 2mg Film-Coated tablets: opadry pink 03B84727 (hypromellose 6cps, titanium dioxide (E171), macrogol, iron oxide red (E172), iron oxide yellow (E172)).

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

Ropinirole 0.25mg Film-coated tablets are white irregular hexagonal shape film-coated tablets, debossed 'W' on one side and '154' on the other.
Ropinirole 0.5mg Film-coated tablets: are yellow irregular hexagonal shape film-coated tablets, debossed 'W' on one side and '155' on the other.
Ropinirole 1mg Film-coated tablets: are green irregular hexagonal shape film-coated tablets, debossed 'W' on one side and '171' on the other.
Ropinirole 2mg Film-coated tablets: are pale yellowish pink irregular hexagonal shape film coated tablets, debossed 'W' on one side and '172' on the other.

These tablets are available in:
• blister packs of 12, 28 or 100 tablets
• HDPE container with child resistant cap of 30 or 84 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Austin McNeil Ltd., 772 Fulham Road, London, SW6 5SJ, United Kingdom.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

These medicinal products are authorised in the Member States of the EEA under the following names:

UK: Ropinirole 0.25, 0.5, 1 and 2mg Film-Coated Tablets

Cyprus: Ropinirole 0.25, 0.5, 1 and 2mg Film-Coated Tablets

Malta: Ropinirole 0.25, 0.5, 1 and 2mg Film-Coated Tablets

Other formats:
<[To be completed nationally] >

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