

Package leaflet: Information for the Patient

Ropinirole SR 2mg prolonged-release tablets
Ropinirole SR 3mg prolonged-release tablets
Ropinirole SR 4mg prolonged-release tablets
Ropinirole SR 8mg prolonged-release 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. This includes any possible side effects not listed in this leaflet. (See section 4).

What is in this leaflet:

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

1. What Ropinirole SR prolonged-release tablets is and what it is used for

The active substance in Ropinirole SR prolonged-release 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 SR prolonged-release tablets is used to treat Parkinson's disease in adults.

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.

2. What you need to know before you take Ropinirole SR prolonged-release tablets

Do not take Ropinirole SR prolonged-release tablets

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Ropinirole SR prolonged-release tablets:

- if you have a serious heart complaint
- if you have a history of or currently have a serious mental health problem
- if you have a history of or have experienced any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour, see section 4)

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, lack of energy, sweating or pain after stopping or reducing your Ropinirole SR prolonged-release tablets treatment. 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 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.

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 SR prolonged-release tablets . Your doctor may need to adjust or stop your dose.

The prolonged release-tablets are designed to release the active substance over a 24hr period. If you have a condition where your medicine passes through your body too quickly, e.g., diarrhoea, the tablet(s) may not dissolve completely and may not work properly. You may see tablet(s) in your stool. If this happens, let your doctor know as soon as possible.

Children and adolescents

Ropinirole SR prolonged-release tablets is not recommended for use in children and adolescents below 18 years of age.

Other medicines and Ropinirole SR prolonged-release tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any herbal medicines or any other medicines you obtained without a prescription.

Some medicines can affect the way Ropinirole SR prolonged-release tablets works or make it more likely that you'll have side effects. Ropinirole SR prolonged-release tablets can also affect the way some other medicines work.

These include:

- the anti-depressant, fluvoxamine
- HRT (hormone replacement therapy)
- medicines 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
- 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. You will require additional blood tests if you are taking these medicines with Ropinirole SR prolonged-release tablets:

- Vitamin K antagonists (used to reduce blood clotting) such as Warfarin (coumadin).

Tell your doctor if you start smoking, or give up smoking, while you are taking Ropinirole SR prolonged-release tablets. Your doctor may need to adjust your dose.

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 or pharmacist for advice before taking this medicine.

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

Ropinirole SR prolonged-release tablets is not recommended if you are breast-feeding, as it can affect your milk production.

Driving and using machines

Ropinirole SR prolonged-release tablets can make you feel drowsy or dizzy.

It can make people feel extremely sleepy, and it sometimes makes people fall asleep very suddenly without warning.

Ropinirole SR prolonged-release tablets can cause hallucinations (seeing, hearing or feeling things that are not there).

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 sure you are no longer affected. Talk to your doctor if this causes problems for you.

Ropinirole SR prolonged-release tablets 2 mg and 3 mg prolonged release tablets

Ropinirole SR prolonged-release tablets contains lactose

Ropinirole SR prolonged-release tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ropinirole SR prolonged-release tablets 3 mg and 4 mg prolonged release tablets

Ropinirole SR prolonged-release tablets contains sunset yellow (E110)

Ropinirole SR prolonged-release tablets contains a colouring called sunset yellow (E110), which may cause allergic reactions.

3. How to take Ropinirole SR prolonged-release tablets

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

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

The recommended starting dose is 2 mg ropinirole once daily for the first week. Your doctor may increase your dose to 4 mg ropinirole once daily, from the second week of treatment. If you are very elderly your doctor may increase your dose more slowly. After that, the doctor may adjust your dose until you are taking the dose that is best for you. Some people take up to 24 mg ropinirole each day.

Do not take more Ropinirole SR prolonged-release tablets than your doctor has recommended. It may take a few weeks for Ropinirole SR prolonged-release tablets to work for you.

If at the start of your treatment, you experience side effects that you find difficult to tolerate, speak to your doctor. Your doctor may advise you to switch to a lower dose of Ropinirole film-coated (immediate-release) tablets which you will take three times a day.

If you are switching from Ropinirole film-coated (immediate-release) tablets

Your doctor will base your dose of Ropinirole SR prolonged-release tablets on the dose of Ropinirole film-coated (immediate-release) tablets you were taking.

Take your Ropinirole film-coated (immediate-release) tablets as normal the day before you switch. Then take your Ropinirole SR prolonged-release tablets prolonged-release tablets next morning and do not take any more ropinirole film-coated (immediate-release) tablets.

Method of administration

Ropinirole SR prolonged-release tablets is for oral use.

Take Ropinirole SR prolonged-release tablets once a day, at the same time each day. Swallow your tablets whole, with a glass of water. Do not break, chew or crush the tablets - if you do, there is a danger you could overdose, because the medicine will be released into your body too quickly. You can take Ropinirole SR prolonged-release tablets with or without food, as you prefer.

If you take more Ropinirole SR prolonged-release tablets than you should

Contact a doctor or pharmacist immediately. If possible, show them the Ropinirole SR prolonged-release tablets pack.

Someone who has taken an overdose of Ropinirole SR prolonged-release 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 SR prolonged-release tablets

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

If you have missed taking Ropinirole SR prolonged-release tablets for one day or more, ask your doctor for advice on how to start taking it again.

If you stop taking Ropinirole SR prolonged-release tablets

Do not stop taking Ropinirole SR prolonged-release tablets without advice.

Take Ropinirole SR prolonged-release tablets for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking Ropinirole SR prolonged-release 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 SR prolonged-release 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, this medicine can cause side effects, although not everybody gets them.

The side effects of Ropinirole SR prolonged-release 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 are worried about side effects, talk to your doctor.

Very common side effects: may affect more than 1 in 10 people

- fainting
- feeling drowsy
- feeling sick (nausea).

Common side effects: may affect up to 1 in 10 people

- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- hallucinations (sensing things that are not really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- constipation
- swelling of the legs, feet or hands.

Uncommon side effects: 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
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)
- Hiccups

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 blood tests
- act in an aggressive manner
- excessive use of Ropinirole SR prolonged-release tablets (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome)
- depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Ropinirole SR prolonged-release tablets treatment.
- 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).
- spontaneous penile erection

If you're taking Ropinirole SR prolonged-release tablets with L-dopa

People who are taking Ropinirole SR prolonged-release tablets 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 SR prolonged-release tablets.
Tell your doctor if this happens, as your doctor may need to adjust the dose 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. This includes any side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Ropinirole SR prolonged-release tablets

- 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/(bottle) and the carton. The expiry date refers to the last day of that month.
- Store below 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.

6. Contents of the pack and other information

What Ropinirole SR prolonged-release tablets contains

- The active substance is Ropinirole.
 - *Ropinirole SR prolonged-release tablets 2mg prolonged release tablets;*
Each tablet contains 2 mg ropinirole (as 2.28 mg ropiniroleropinirole hydrochloride) ropinirole
 - *Ropinirole SR prolonged-release tablets 3mg prolonged release tablets;*
Each tablet contains 3 mg ropinirole (as 3.42 mg ropiniroleropinirole hydrochloride) ropinirole
 - *Ropinirole SR prolonged-release tablets 4mg prolonged release tablets;*
Each tablet contains 4 mg ropinirole (as 4.56 mg ropiniroleropinirole hydrochloride) ropinirole
 - *Ropinirole SR prolonged-release tablets 8mg prolonged release tablets;*
Each tablet contains 8 mg ropinirole (as 9.12 mg ropiniroleropinirole hydrochloride) ropinirole

The other ingredients are:

Tablet cores:

Ammonio Methacrylate Copolymer, Type B, Hydroxypropylmethyl cellulose, Sodium Lauryl Sulfate, Copovidone K25.2 -30.8, Magnesium stearate

Film coats:

2mg: Lactose monohydrate, Hypromellose, Titanium dioxide (E171), Triacetin, Iron oxide red (E172)

3mg: Lactose monohydrate, Titanium dioxide (E171), Hypromellose, Macrogol 4000, Carmine (E120), Indigo carmine aluminium lake (E132), Sunset yellow aluminium lake (E110)

4mg: Hypromellose, Titanium dioxide (E171), Sunset yellow aluminium lake (E110), Macrogol 400, Indigo carmine aluminium lake (E132)

8mg: Hypromellose, Titanium dioxide (E171), Macrogol 400, Iron oxide red (E172), Iron oxide black (E172), Iron oxide yellow (E172)

What Ropinirole SR prolonged-release tablets looks like and contents of the pack

Ropinirole SR prolonged-release tablets 2mg are pink, round biconvex prolonged-release tablets with approximately 6.8 mm in diameter and 5.5 mm in thickness.

Ropinirole SR prolonged-release tablets 3mg are purple round biconvex prolonged-release tablets with approximately 8.1 mm in diameter and 4.7 mm in thickness.

Ropinirole SR prolonged-release tablets 4mg are light brown oval biconvex prolonged-release tablets with approximate dimensions 12.6 x 6.6 mm and 5.3 mm in thickness

Ropinirole SR prolonged-release tablets 8mg are red to reddish brown, oval biconvex prolonged-release tablets with approximate dimensions: 19.2×10.2 mm and 5.2 mm in thickness.

Ropinirole SR prolonged-release tablets is available in packs of 28 or 84 prolonged release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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