

Swallow the Ropinirole tablets whole, with a glass of water.

You can take Ropinirole with or without food. If you take it with food, you may be less likely to feel sick (nauseous).

Ropinirole is usually taken just before bedtime, but you can take it up to 3 hours before you go to bed.

Elderly
Ropinirole dose should be individually titrated in patients over 65 years old, with careful monitoring of tolerability, to the optimal clinical response.

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, hallucinations.

If you forget to take Ropinirole
Do not take extra tablets or a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

Parkinson's disease: If you have missed taking Ropinirole for one day or more, ask your doctor for advice on how to start taking it again.

Restless legs syndrome: If you have missed taking Ropinirole for more than a few days, ask your doctor for advice on how to start taking it again.

If you stop taking ropinirole
Do not stop taking ropinirole without advice.
Take Ropinirole for as long as your doctor recommends.
Do not stop unless your doctor advises you to. If you suddenly stop taking ropinirole your Parkinson's disease symptoms or restless legs syndrome 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 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 are worried about side effects, talk to your doctor.

Stop taking Ropinirole and tell your doctor immediately or go to the casualty department at your nearest hospital, if the following happens:

- 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).

These are very serious side effects with unknown frequency. You may need urgent medical attention or hospitalisation.

You may experience the following side effects (frequency not known: cannot be estimated from the available data):

- 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)
- 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)
- aggression
- episodes of overactivity, elation or irritability
- depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your ropinirole treatment

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

Parkinson's disease
Following side effects have been reported, when ropinirole is used to treat 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 are not real)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- swelling of the legs, feet and 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)
- low blood pressure (hypotension)
- 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

Not known: frequency cannot be estimated from the available data

- changes in liver function, which have shown up in blood tests.
- Spontaneous penile erection

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 (dyskinesia) 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.

Restless legs syndrome:
The following side effects have been reported, when ropinirole is used to treat 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).
- Low blood pressure (hypotension)
- hiccups

Very rare: may affect up to 1 in 10,000 people

- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- changes in liver function which have shown up in blood tests.

Not known: frequency cannot be estimated from the available data
Some patients may have the following side effects

- mental problems (other than hallucinations), such as severe confusion (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- spontaneous penile erection

Ropinirole 0.5/2 mg film-coated tablets: lecithin (soya) may cause very rarely allergic reactions.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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

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

Ropinirole 0.25 mg: Do not store above 25°C. Store in the original container.
Ropinirole 0.5 mg: Do not store above 25°C. Store in the original container.
Ropinirole 2 mg: Do not store above 30°C. Store in the original container.

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 is ropinirole hydrochloride.

- Each Ropinirole 0.25 mg film-coated tablet contains 0.285 mg ropinirole hydrochloride, equivalent to 0.25 mg ropinirole.
- Each Ropinirole 0.5 mg film-coated tablet contains 0.57 mg ropinirole hydrochloride, equivalent to 0.5 mg ropinirole.
- Each Ropinirole 2 mg film-coated tablet contains 2.28 mg ropinirole hydrochloride, equivalent to 2 mg ropinirole.

The other ingredients are lactose monohydrate, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium and magnesium stearate.

The tablet coating contains:

- Ropinirole 0.25 mg (Opadry II 85F18422): poly (vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350 and talc.
- Ropinirole 0.5 mg (Opadry II 85G32558): poly(vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, lecithin (soya) (E322), iron oxide yellow (E172) and iron oxide black (E172).
- Ropinirole 2 mg (Opadry II 85G34363): poly(vinyl alcohol) – partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, lecithin (soya) (E322), carmine (E120), iron oxide yellow (E172) and iron oxide black (E172).

What Ropinirole looks like and contents of the pack
Ropinirole 0.25 mg is a white, round slightly arched film-coated tablet, debossed "R 0.25" on one side and plain on the other.

Ropinirole 0.5 mg is a yellow, round slightly arched film-coated tablet, debossed "R 0.5" on one side and plain on the other.

Ropinirole 2 mg is a pink, round slightly arched film-coated tablet, debossed "R 2" on one side and plain on the other.

Ropinirole 0.25 mg is available in pack sizes of 12, 15, 21, 24, 30, 60, 81, 84, 90, 100, 126, 210 and 50 unit dose blisters (hospital presentation pack).
Ropinirole 0.5 mg is available in pack sizes of 15, 21, 28, 30, 60, 84, 90, 100 and 126.
Ropinirole 2 mg is available in pack sizes of 15, 21, 28, 30, 60, 84, 90 and 100 and 50 unit dose blisters (hospital pack).

Not all pack sizes may be marketed.

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