

LEAFLET: INFORMATION FOR THE USER

Ropinirol Viatris 0.25 mg, film-coated tablets
Ropinirol Viatris 0.5 mg, film-coated tablets
Ropinirol Viatris 1 mg, film-coated tablets
Ropinirol Viatris 2 mg, film-coated tablets

Ropinirol (as hydrochloride)

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any further questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Ropinirol Viatris and what is it used for?

The active substance in this medicine is ropinirole, which belongs to a group of medicines called dopamine agonists. Dopamine agonists affect the brain in the same way as the natural substance dopamine.

This medicine is used in the treatment of Parkinson's disease.

People with Parkinson's disease have a low amount of dopamine in some parts of their brains. This medicine has a similar effect to natural dopamine, helping to reduce the symptoms of Parkinson's disease.

This medicine is also used for the treatment of moderate to severe 'idiopathic Restless Legs Syndrome'. Moderate to severe 'Restless Legs Syndrome' is characteristic of patients who have sleep disturbances or experience severe discomfort in their legs or arms.

'Restless Legs Syndrome' is a condition characterized by an irresistible urge to move the legs and sometimes the arms, usually in combination with a uncomfortable feeling such as tingling, burning, or prickling sensation. These feelings appear during periods of rest or inactivity such as sitting or lying down, especially in bed, and are worse in the evening or at night.

Usually, relief can only be achieved by walking or moving the affected limbs, which often leads to sleep disturbances.

This medicine relieves the discomfort and reduces the need to move the limbs (symptoms that disrupt sleep).

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

If you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you have a severe kidney disease.

If you have a liver disorder.

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

When should you be extra careful with this medicine?

Consult your doctor or pharmacist before using this medicine. Medicines are not always suitable for everyone. Your doctor needs to know before you use this medicine if you currently suffer or have suffered from any of the following conditions:

you are pregnant or think you might be pregnant;

you are breastfeeding;

you are under 18 years of age;

you have a serious heart condition;

you suffer from severe mental health problems

you notice that you develop unusual behavior and/or urges (such as an excessive urge to gamble or an increased sexual need and/or sexual behavior);

you are intolerant to certain 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 treatment with this medicine (this is called dopamine agonist withdrawal syndrome or DAWS). If the problems persist for more than a few weeks, your doctor may need to adjust your dosage.

Tell your doctor if you or someone in your family notices that you develop the desire to behave in an unusual way and if you cannot resist the impulse, drive, or temptation to perform certain activities that may be harmful to yourself or others. These are called impulse control disorders and may include behaviors such as addictive gambling, excessive eating, an abnormally high sexual drive, or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your treatment.

Tell your doctor if you or your family/caregiver notice that you develop periods of overactivity, elation, or irritability (symptoms of mania). These may occur with or without the symptoms of abnormalities in controlling impulses (see above). Your doctor may need to adjust or stop your dosage.

Tell your doctor if you think any of these situations apply to you. Your doctor may decide that this medicine is not suitable for you, or that you need extra monitoring while using it.

While using this medicine

Tell your doctor if you or your family notice that you develop unusual behavior (such as an unusual urge to gamble or an increased sexual need and/or sexual behavior) while using this medicine. Your doctor may need to adjust or discontinue your dosage.

Driving and using machines

This medicine can make you drowsy. It can make people feel very sleepy and sometimes people fall asleep very suddenly without warning. This medicine can cause hallucinations (seeing, hearing, or feeling things that are not there). If you suffer from this, you should not drive or operate machines.

If you could suffer from any of these side effects, you should not drive, operate machines, or put yourself in a situation where drowsiness or falling asleep could cause a risk of serious injury or death to yourself (or other people). Do not engage in such activities until you no longer have these symptoms.

Tell your doctor if this is a problem for you.

Are you taking any other medicines?

Are you taking any other medicines besides Ropinirol Viatris, or have you done so recently, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist. This also applies to herbal medicines or other medicines that you can obtain without a prescription.

Some medicines can affect the way Ropinirol Viatris works or increase the chance that you will experience a side effect. Ropinirol Viatris can also affect the action of other medicines.

These medicines include:

- the antidepressant medicine fluvoxamine
- medications for other mental health problems such as sulpiride
- hormone replacement therapy (also called HRT)
- metoclopramide, a drug used to treat nausea and heartburn
- the antibiotics ciprofloxacin or enoxacin
- any other medication for the treatment of Parkinson's disease or "Restless Legs Syndrome".

Tell your doctor if you are using or have recently used any of these medications.

Extra blood will need to be taken if you use these medications in combination with ropinirole:
vitamin K antagonists (used to make the blood less likely to clot) such as warfarin (coumadin)

Smoking and this medicine

Tell your doctor if you have stopped or started smoking while using this medicine. Your doctor may find it necessary to adjust your dosage.

What should you pay attention to with food and drink?

If you take this medicine with food, you are less likely to feel nauseous or vomit. It is best to take this medicine with food, if possible.

Pregnancy and breastfeeding

The use of this medicine during pregnancy is not recommended unless your doctor advises you that the benefit to you of taking this medicine outweighs the possible risk of harm to your unborn child. This medicine is not recommended if you are breastfeeding, as it may affect your milk production.

Tell your doctor immediately if you are pregnant, think you may be pregnant, or are planning to become pregnant. Your doctor will also advise you if you are breastfeeding or planning to breastfeed. Your doctor may then recommend that you stop using this medicine.

Important information about some of the ingredients in Ropinirole

Ropinirole tablets contain a small amount of a sugar called lactose.

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

You may be prescribed this medicine as the only medication to treat the symptoms of Parkinson's disease or Restless Legs Syndrome. This medicine can also be used in combination with another medicine called L-dopa (also known as levodopa).

Do not give this medicine to children. This medicine is normally not prescribed to individuals under 18 years of age.

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

The exact dosage of this medicine that users take can vary. Your doctor will decide what dose you should take each day, and you should follow this instruction. When you first start with this medicine, the dosage you use will be gradually increased.

How much of this medicine should you take

Parkinson's disease

It may take some time to determine the most suitable dosage of this medicine for you. The usual starting dose of ropinirole is 0.25 mg three times a day during the first week. After this, your doctor may increase the dose weekly over the next 3 weeks. After this, your doctor may adjust the dose until you are using the dose that works best for you. The usual dose is 1 mg to 3 mg three times a day (which corresponds to a total daily dose of 3 mg to 9 mg). If your symptoms of this disease do not improve sufficiently, your doctor may decide to gradually increase the dose. Some people take up to 8 mg of ropinirole three times a day (24 mg total daily dose).

If you are also using other medications for the treatment of Parkinson's disease, your doctor may advise you to gradually reduce the dosage of the other medication. If you are using L-dopa, you may experience uncontrolled movements (dyskinesia) when you start using Ropinirol. Tell your doctor if this happens, as your doctor may need to adjust the dosage of your medication.

Restless Legs Syndrome

Take this medicine once a day by mouth, at the same time every day. This medicine is usually taken before bedtime but can also be taken up to three hours before bedtime.

The starting dose is 0.25 mg once a day. After two days, your doctor may increase the dose to 0.5 mg once a day for the rest of your first treatment week. After this, your doctor may increase the dose weekly by 0.5 mg over the next 3 weeks to a dose of 2 mg per day. In some patients with insufficient improvement, the dose can be slowly increased to a maximum of 4 mg per day. After three months of treatment with this medicine, your doctor may adjust the dose or stop the treatment, depending on your symptoms and how you feel.

Do not take more of this medicine than your doctor has advised.
It may take a few weeks before you feel improvement with Ropinirol.

What to do if your symptoms worsen

Occasionally, individuals taking this medicine may experience worsening of their Restless Legs Syndrome symptoms. For example, the symptoms may start earlier in the day or appear after a short period of rest. Or the symptoms may occur in other parts of the body, such as the arms.

See your doctor if your symptoms worsen.

Taking your dose of Ropinirol Viatrix

Take your Ropinirol Viatrix tablet(s) whole with a glass of water. It is recommended to take this medicine with food, as this reduces the chance of nausea.

Have you used too much of this medicine?

Contact your doctor or pharmacist immediately. If possible, show them the packaging of this medicine.

Someone who has taken an overdose of ropinirole may experience the following symptoms: nausea, vomiting, dizziness (or the feeling of spinning), drowsiness, fatigue (mental or physical tiredness), fainting, hallucinations.

Did you forget to use this medicine?

Do not take extra tablets or a double dose to make up for a forgotten dose. Take the next tablet at the usual time.

If you have forgotten to take this medicine for a day or longer, ask your doctor for advice on how to start taking it again.

If you stop using this medicine

Take this medicine for as long as your doctor has advised you. Do not stop using it unless your doctor advises you to.

If you suddenly stop using this medicine, the symptoms of Parkinson's disease may quickly worsen. A sudden discontinuation could lead to a medical condition called 'neuroleptic malignant syndrome'. This condition can pose a serious health risk. Symptoms include: akinesia (loss of muscle movement), stiff muscles, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, reduced consciousness (e.g., coma).

If you need to stop using this medicine, your doctor will gradually reduce your dosage.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The side effects of this medicine are particularly likely to occur when you start your treatment or when the dosage has just been increased. The side effects are generally mild and may become less bothersome after you have used the dose for some time. Tell your doctor if you are concerned about side effects.

Very common side effects

These may occur in more than 1 in 10 people using Ropinirole:

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

Common side effects

These may occur in up to 1 in 10 people using Ropinirole:

- hallucinations (seeing things that are not really there);
- being sick (vomiting);
- dizziness (spinning sensation);
- heartburn;
- stomach pain;
- swelling of the legs, feet, or hands;
- nervousness;
- worsening of "Restless Legs Syndrome" (symptoms may occur earlier than usual or be more intense, or they may affect previously unaffected limbs such as the arms or return in the early morning).

Sometimes occurring side effects

These may occur in up to 1 in 100 people who use Ropinirole:

- low blood pressure (hypotension);
- dizziness or fainting, especially when standing up suddenly (this is caused by a sudden drop in blood pressure);
- feeling very sleepy during the day (extreme sleepiness);
- suddenly falling asleep without feeling sleepy beforehand (episodes of unexpected sleep onset);
- mental problems such as delirium (severe confusion), delusions (unreasonable thoughts), or paranoia (unreasonable suspicions);

hiccups.

In some patients, the following side effects may occur (frequency not known; cannot be estimated from the available data)

allergic reaction such as red, itchy swellings on the skin (hives), swelling of the face, lips, mouth, tongue, or throat that may cause difficulty swallowing or breathing, rash, or intense itching (see section 2);

aggression;

excessive use of Ropinirole (craving for larger doses of dopaminergic drugs than needed to treat motor symptoms, known as dopamine dysregulation syndrome);

after stopping or reducing treatment with ropinirole, the following side effects may occur: Depression, apathy, anxiety, fatigue, sweating, or pain (also known as dopamine agonist withdrawal syndrome (DAWS) or dopamine agonist withdrawal syndrome);

change in liver function, as shown in blood tests;

spontaneous penile erection.

You may experience the following side effects:

the inability to resist an impulse, urge, or temptation to perform an activity that could be harmful to you or others, including:

- o a strong urge to gamble excessively despite serious consequences for you personally or for your family
- o altered or increased sexual interest, which causes concern for you or others, for example, an increased sexual drive;
- o uncontrolled and excessive shopping or spending;
- o binge eating (eating large amounts of food in a short period) or compulsive eating (eating more food than needed to satisfy your hunger).

periods of overactivity, elation, or irritability

Tell your doctor if you experience one or more of these symptoms, as it can be discussed what the best way is to reduce them.

If you use this medicine in combination with L-dopa

People using this medicine in combination with L-dopa may develop other side effects over time:

uncontrolled movements (dyskinesia) are a very common side effect. If you are using L-dopa, you may experience uncontrolled movements (dyskinesia) when you start using ropinirole. Tell your doctor if this happens, as your doctor may need to adjust your medication dosage.

confusion is a common side effect.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (Website: www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the packaging after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

This medicine does not require any special storage conditions.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is ropinirole.
Each film-coated tablet contains 0.25 mg, 0.5 mg, 1 mg, or 2 mg ropinirole (as hydrochloride).
- The other substances in this medicine are: microcrystalline cellulose, lactose monohydrate (see section 2 "Ropinirol Viatriis contains lactose"), croscarmellose sodium, hypromellose, magnesium stearate.

The film coating contains:

0.25 mg: hypromellose, titanium dioxide (E171), macrogol, polysorbate.

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

1 mg: hypromellose, macrogol, iron oxide (E172), titanium dioxide (E171), indigocarmine

(E132). 2 mg: hypromellose, titanium dioxide (E171), macrogol, iron oxide red (E172), iron oxide yellow (E172).

What does Ropinirol Viatriis look like and what is in a package? Your medicine is provided as a film-coated tablet.

Ropinirol Viatriis 0.25 mg: white to off-white capsule-shaped, biconvex, film-coated tablets with a score line on both sides.

Ropinirol Viatriis 0.5 mg: yellow, capsule-shaped, biconvex, film-coated tablets with a score line on both sides.

Ropinirole Viatriis 1 mg: green, capsule-shaped, biconvex, film-coated tablets with a score line on both sides.

Ropinirole Viatriis 2 mg: light pink, capsule-shaped, biconvex, film-coated tablets with a score line on both sides.

The tablet can be divided into equal doses.

Ropinirole Viatriis is available in an HDPE bottle with PP closure of 12 (only 0.25 mg), 21, 28, 84, and 126 tablets.

Marketing authorization holder and manufacturer

Registration holder
Viatriis Ltd

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Ropinirol Viatris is registered under the following numbers:
RVG 34856 (0.25 mg), RVG 34857 (0.5 mg), RVG 34858 (1 mg), RVG 34859 (2 mg)

This medicine is registered in EEA member states under the following names:

Belgium:	'Ropinirole Viatris 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg film-coated tablets'
Czech Republic:	'Ropinirole Viatris 2 mg potahované tablety'
Denmark:	'Ropinirol Viatris 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg'
France:	'Ropinirole Viatris 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg comprimé pelliculé'
Germany:	'Ropinirol dura 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg Film-coated tablets'
Italy:	'Ropinirolo Mylan Generics 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg film-coated tablets'
	film-coated
Portugal:	'Ropinirole Mylan 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg'
Slovakia:	'Ropinirol Viatris 1 mg/ 2 mg'
Netherlands:	'Ropinirol Viatris 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg film-coated tablets'
United Kingdom (Northern Ireland):	'Ropinirole 0.25/ 0.5 mg/ 1 mg/ 2 mg film-coated tablets'

This leaflet was last approved in August 2023.