

## LEAFLET: INFORMATION FOR THE PATIENT

Ropinirole Retard Viatris 2 mg, prolonged-release tablets  
Ropinirole Retard Viatris 4 mg, prolonged-release tablets  
Ropinirole Retard Viatris 8 mg, prolonged-release tablets  
Ropinirole

Read the entire 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.
- Do you have any questions? 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 listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Ropinirole Retard Viatris and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How should you use this medicine?
4. Possible side effects
5. How should you store this medicine?
6. Contents of the packaging and other information

### 1. What is Ropinirole Retard Viatris and what is it used for?

The active substance in Ropinirole Retard Viatris 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.

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

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

When should you not use this medicine?

- you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6
- you have a severe kidney disease
- 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?

Contact your doctor or pharmacist before using this medicine if:

- you are pregnant or think you might be pregnant
- you are breastfeeding
- you are under 18 years old
- you have a severe heart condition
- you suffer from severe mental health problems
- you cannot tolerate certain sugars (such as lactose)

Your doctor may decide that this medicine is not suitable for you, or that you need extra monitoring while using it.

Tell your doctor if you or your family/caregiver notice that you develop periods of overactivity, elation, or irritability (symptoms of mania). These can occur with or without symptoms of impulse control disorders (being unable to resist impulses to do something that could be harmful, see above). Your doctor may need to adjust or stop your dosage.

While using this medicine

Tell your doctor if you or your family/caregiver notice that you develop the tendency or desire to behave in ways that are unusual for you or if you cannot resist the impulse, urge, or temptation to do things that could harm yourself or others. Such behavior is called an impulse control disorder and can include gambling addiction, excessive eating or spending, an abnormally high sex drive, or an increase in sexual thoughts or feelings. Your doctor may need to adjust your dosage or stop the treatment.

After stopping or reducing this medication

Tell your doctor if you experience symptoms such as depression, apathy (indifference), restlessness, fatigue, sweating, or pain after stopping treatment with ropinirole or reducing the dosage (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 the treatment.

Smoking and this medication

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

Are you using any other medications?

Are you using any other medications besides Ropinirol Retard Viatris, have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist. Remember to tell your doctor or pharmacist if you start using a new medication during treatment with this medication.

Some medications can affect how Ropinirol Retard Viatris works or increase the chance of experiencing a side effect. This medication can also affect how some other medications work. These medications include:

- antidepressant fluvoxamine, a medication for, among other things, a depressive mood
- medications for other mental health problems, for example, sulpiride
- hormone replacement therapy
- metoclopramide, a medication used to treat nausea and heartburn
- the antibiotics ciprofloxacin or enoxacin
- any other medication to treat Parkinson's disease

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 Ropinirol Retard Viatris:

vitamin K antagonists (used to make the blood less likely to clot) such as warfarin (coumadin).

### Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication. The use of this medication during pregnancy is not recommended unless your doctor advises you that the benefit of taking this medication outweighs the possible risk of harm to your unborn child.

Your doctor will also advise you if you are breastfeeding or planning to do so. This medication is not recommended for use if you are breastfeeding, as it may affect your milk production. Your doctor may advise you to stop using this medication.

### Driving and using machines

This medication can make you feel drowsy. It can cause extreme drowsiness in some people, and sometimes people may fall asleep suddenly and without warning.

If you experience any of these side effects, you should not drive, operate machinery, or put yourself in a situation where drowsiness or falling asleep could put you (or others) at risk of serious injury or death. Do not engage in these activities until these symptoms no longer occur.

Ropinirole can cause hallucinations (seeing, hearing, or feeling things that are not there). If you experience this, you should not drive or use machines.

Ropinirole Retard Viatris contains lactose and sodium

Ropinirole Retard Viatris contains 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 medication.

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

### 3. How to use this medication?

Always use this medication exactly as your doctor or pharmacist has told you. Contact your doctor or pharmacist if you are unsure about the correct use.

You may be prescribed this medication as the only medication to treat your symptoms of Parkinson's disease. You may also be prescribed this medication together with another medication called L-dopa (also known as levodopa). When using L-dopa, you may experience involuntary, jerky movements when you first start using ropinirole. Tell your doctor if this happens, as it may be necessary for your doctor to adjust the dosage of the medications you are taking.

Ropinirole Retard Viatris tablets are designed to release medication over a period of 24 hours. If you have a condition where your medication passes through your body too quickly, such as diarrhea, the tablet(s) may not dissolve completely and may not work properly. You may see tablet(s) in your stool. If this happens, contact your doctor as soon as possible.

Use in children and adolescents under 18 years

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

How much of this medication should you use?

It may take some time to determine the most suitable dosage for you.

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

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If you experience side effects at the start of treatment that are difficult to tolerate, you should inform your doctor. Your doctor may then advise you to switch to a lower dosage of ropinirole film-coated tablets (immediate release), which you should take three times a day.

It may take a few weeks for this medication to work for you. Do not take more tablets than your doctor has advised.

Taking your dosage

Take this medication once a day at the same time. You can take this medication with or without food, according to your preference.

Swallow this medication whole with a glass of water. Do not break, chew, or crush. If you do, there is a risk of overdose because the medication is released too quickly in your body.

If you are switching from ropinirole film-coated tablets with immediate release  
Your doctor will base your dosage of the extended-release tablets on the dosage of ropinirole film-coated tablets (immediate release) you were using.

Take your ropinirole film-coated tablets (immediate release) as usual on the day before you switch. Then take the Ropinirol Retard Viatris extended-release tablets the next morning and do not take any more ropinirole film-coated tablets (immediate release).

Have you used too much of this medication?

Contact your doctor or pharmacist immediately. Show them the packaging of this medication if possible.

Someone who has taken an overdose of this medication may experience the following symptoms: nausea, vomiting, dizziness (feeling of spinning), drowsiness, mental or physical fatigue, fainting, perceptions (seeing, hearing, smelling) of things that are not there (hallucinations).

Have you forgotten to use this medication?

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

If you have forgotten to take this medication for a day or longer, ask your doctor for advice on how to resume taking this medication.

If you stop using this medication

Do not stop using this medication without consulting your doctor. Take this medication for as long as your doctor has advised you. Do not stop using it unless your doctor advises you to do so. If you suddenly stop using this medication, the symptoms of Parkinson's disease may quickly become much worse. A sudden discontinuation can cause you to develop a condition called 'Neuroleptic Malignant Syndrome'. This can pose a serious risk to your health. The symptoms are: akinesia (loss of muscle mobility), stiff muscles, fever, unstable blood pressure, tachycardia (rapid heartbeat), confusion, loss of consciousness (e.g., coma).

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

Do you have any other questions about using this medication? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medications, this medication can have side effects, although not everyone experiences them.

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

If the following occurs, do not take more of this medication. Contact your doctor immediately or go to the emergency department at the nearest hospital:

Unknown (cannot be determined from the available data):

hypersensitivity reactions including itchy skin rash, swollen face, lips, throat, or tongue that may cause difficulty swallowing or breathing, rash and itching.

Other side effects include:

Very common (occur in more than 1 in 10 users):

fainting  
feeling drowsy  
feeling sick (nausea)

Common (occur in less than 1 in 10 users):

perceptions (seeing, hearing, smelling, feeling) of things that are not there (hallucinations)  
vomiting  
dizziness (feeling of spinning)  
suddenly falling asleep without feeling drowsy beforehand (episodes of unexpected sleep onset)  
heartburn  
stomach pain  
constipation  
swelling in the legs, feet, or hands

Sometimes (occur in less than 1 in 100 users):

feeling dizzy or weak, especially when standing up suddenly (this is caused by a sudden drop in blood pressure)  
being very sleepy all day  
mental problems such as delirium (sudden, severe confusion), hallucinations (seeing, feeling, or hearing things that are not there) or paranoia (feeling watched, followed, or threatened without reason)  
hiccups.

Unknown (cannot be determined from the available data):

aggression  
changes in liver function shown by blood tests  
craving high doses of dopaminergic medications, more than needed to control the body's motor functions, known as 'dopamine dysregulation syndrome'.  
after stopping or reducing treatment with Ropinirole Retard Viatrix, the following side effects may occur: Depression, apathy, restlessness, fatigue, sweating or pain (also known as dopamine agonist withdrawal syndrome (DAWS)).  
Unusual excitement, euphoria, or irritability, overactive or uninhibited behavior (mania).  
spontaneous penile erection.

You may experience the following side effects:

Inability to resist the impulse (impulse control disorders) to do something that could be harmful, for example:

a strong impulse to gamble excessively, despite the serious consequences for you or your family  
a changed or increased sexual interest or behavior that you or others are very concerned about, such as an increased need for sex  
an uncontrollable need to buy or spend excessively  
binge eating (eating large amounts of food in a short time) or compulsive eating (eating more than normal and more than needed to satisfy your hunger)

Tell your doctor if you notice such behavior. He/she will discuss with you how these symptoms can be treated or reduced.

If you use this medicine in combination with L-dopa

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

uncontrollable, jerky movements are a very common side effect. If you take L-dopa, you may experience uncontrollable movements (dyskinesia) when you first use this

medicine. Tell your doctor if this happens, as they 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](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How to 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 blister pack and box after 'EXP.' It includes a month and a year. The last day of that month is the expiry date.

Store below 30°C.

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 then 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 tablet contains 2, 4, or 8 mg of ropinirole (as hydrochloride).

The other substances in this medicine are: hypromellose, croscarmellose sodium, maltodextrin, lactose monohydrate, hydrogenated castor oil, silicon dioxide, magnesium stearate Pigment mixture:

[2 mg prolonged-release tablets]: red iron oxide (E172), yellow iron oxide (E172), lactose monohydrate [4 mg & 8 mg prolonged-release tablets]:

red iron oxide (E172), yellow iron oxide (E172), lactose monohydrate, black iron oxide (E172)

##### What does Ropinirol Retard Viatris look like and what is in a package?

Ropinirol Retard Viatris 2 mg, prolonged-release tablets are pink, speckled, and oval with a "2x" marking on one side.

Ropinirol Retard Viatris 4 mg, prolonged-release tablets are brown, speckled, and oval with a "4x" marking on one side.

Ropinirol Retard Viatris 8 mg, prolonged-release tablets are dark pink, speckled, and oval with an "8x" marking on one side.

##### Package sizes:

Ropinirol Retard Viatris prolonged-release tablets are available in blister packs of 21, 28, 30, 42, 56, 84, and 90 prolonged-release tablets.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Viartis Ltd

Damastown Industrial Park

Mulhuddart

Dublin 15

Dublin, Ireland

For information and inquiries:

Mylan B.V.

Krijgsman 20

Amstelveen

Manufacturer

Actavis Ltd

BLB 016, Bulebel Industrial Estate

Zejtun ZTN 3000

Malta

Registered under:

Ropinirol Retard Viartis 2 mg      RVG 118997

Ropinirol Retard Viartis 4 mg      RVG 118999

Ropinirol Retard Viartis 8 mg      RVG 119000

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

Denmark

Aztarol

France

Ropinirole Viartis LP 2mg, 4mg, 8mg, prolonged-release tablet

Italy

Ropinirolo Mylan

Netherlands

Ropinirol Retard Viartis 2 mg, 4 mg, 8 mg, prolonged-release tablets

Portugal

Ropinirol Mylan

United Kingdom

Ropinirole Mylan XL 2 mg, 4 mg, 8 mg Prolonged-release Tablets

This leaflet was last approved in May 2024.

More information about this medicine is available on the website of the Medicines Evaluation Board ([www.cbg-meb.nl](http://www.cbg-meb.nl)).