

Patient Information

Ropinirole (roe PIN i role) Extended-Release Tablets

Important Note: Ropinirole extended-release tablets have not been studied in RLS and are not approved for the treatment of RLS. However, an immediate-release form of ropinirole is approved for the treatment of moderate to severe primary RLS.

What is the most important information I should know about ropinirole extended-release tablets?

Ropinirole extended-release tablets can cause serious side effects including:

- **Falling asleep during normal activities.** You may fall asleep while doing normal activities such as driving a car, doing physical tasks, or using hazardous machinery while taking ropinirole extended-release tablets. You may suddenly fall asleep without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while doing normal activities while taking ropinirole extended-release tablets are greater if you take other medicines that cause drowsiness. Tell your healthcare provider right away if this happens. Before starting ropinirole extended-release tablets, be sure to tell your healthcare provider if you take any medicines that make you drowsy.
- **Fainting.** Fainting can happen, and sometimes your heart rate may be decreased. This can happen especially when you start taking ropinirole extended-release tablets or your dose is increased. Tell your healthcare provider if you faint, feel dizzy or feel light-headed.
- **Decrease in blood pressure.** Ropinirole extended-release tablets can decrease your blood pressure (hypotension), especially when you start taking ropinirole extended-release tablets or when your dose is changed. If you faint or feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down (orthostatic hypotension), this may mean that your blood pressure is decreased. When you change position from lying down or sitting to standing up, you should do it carefully and slowly. Call your healthcare provider if you have any of the symptoms of decreased blood pressure listed above.
- **Increase in blood pressure.** Ropinirole extended-release tablets may increase your blood pressure.
- **Changes in heart rate (decrease or increase).** Ropinirole extended-release tablets can decrease or increase your heart rate.
- **Hallucinations and other psychotic-like behavior.** Ropinirole extended-release tablets can cause or worsen psychotic-like behavior including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking. The chances of having hallucinations or these other psychotic-like changes are higher in people with Parkinson's disease who are taking ropinirole extended-release tablets or taking higher doses of these drugs. If you have hallucinations or any of these other psychotic-like changes, talk with your healthcare provider.
- **Uncontrolled sudden movements.** Ropinirole extended-release tablets may cause uncontrolled sudden movements or make such movements you already have worse or more frequent. Tell your healthcare provider if this happens. The doses of your anti-Parkinson's medicines may need to be changed.
- **Unusual urges.** Some patients taking ropinirole extended-release tablets get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble, increased sexual urges and behaviors, or an uncontrollable urge to shop, spend money, or eat. If you notice or your family notices that you are developing any unusual behaviors, talk to your healthcare provider.
- **Withdrawal Symptoms.** Ropinirole extended-release tablets are dopamine agonist medicines. Dopamine agonist medicines, including ropinirole extended-release tablets, can cause withdrawal symptoms as your dose is slowly lowered (tapered) or when treatment with ropinirole extended-release tablets is stopped. Tell your doctor right away if you get any of the following withdrawal symptoms:
 - fever
 - confusion
 - severe muscle stiffness
 - insomnia
 - depression
 - anxiety
 - fatigue
 - sweating
 - pain
 - feeling like you do not care about things you usually care about (apathy)

After you have stopped taking ropinirole extended-release tablets, your healthcare provider may need to restart you at a low dose of ropinirole extended-release tablets if you get severe withdrawal symptoms.

What are ropinirole extended-release tablets?

Ropinirole extended-release tablets are long-acting prescription medicine containing ropinirole (taken 1 time a day) that is used only to treat Parkinson's disease but not to treat Restless Legs Syndrome (RLS).

Having one of these conditions does not mean you have or will develop the other condition.

You should not be taking more than 1 medicine containing ropinirole. Tell your healthcare provider if you are taking any other medicine containing ropinirole.

It is not known if ropinirole extended-release tablets are safe and effective for use in children younger than 18 years of age.

Do not take ropinirole extended-release tablets if you:

- are allergic to ropinirole or any of the ingredients in ropinirole extended-release tablets. See the end of this page for a complete list of the ingredients in ropinirole extended-release tablets.
- Get help right away if any of the symptoms of an allergic reaction cause problems swallowing or breathing.
Call your healthcare provider if you have any of the symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
 - hives
 - swelling of the face, lips, mouth, tongue, or throat
 - rash
 - itching

Before taking ropinirole extended-release tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have daytime sleepiness from a sleep disorder or have unexpected or unpredictable sleepiness or periods of sleep.
- start or stop taking other medicines while you are taking ropinirole extended-release tablets. This may increase your chances of getting side effects.
- start or stop smoking while you are taking ropinirole extended-release tablets. Smoking may decrease the treatment effect of ropinirole extended-release tablets.
- feel dizzy, nauseated, sweaty, or faint when you stand up from sitting or lying down.
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking ropinirole extended-release tablets.
- have high or low blood pressure.
- have or have had heart problems.
- are pregnant or plan to become pregnant. It is not known if ropinirole extended-release tablets can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ropinirole passes into your breast milk. The amount of breast milk you make may be decreased while taking ropinirole extended-release tablets. Talk to your healthcare provider to decide if you should breastfeed while taking ropinirole extended-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some of these medicines may increase your chances of getting side effects while taking ropinirole extended-release tablets.

How should I take ropinirole extended-release tablets?

- Take ropinirole extended-release tablets exactly as directed by your healthcare provider.
- Take ropinirole extended-release tablets with or without food.
- **Do not** suddenly stop taking ropinirole extended-release tablets without talking to your healthcare provider. If you stop this medicine, you may develop withdrawal symptoms (See “**What is the most important information I should know about ropinirole extended-release tablets?**”)
- Before starting ropinirole extended-release tablets, you should talk to your healthcare provider about what to do if you miss a dose. If you have missed the previous dose and it is time for your next dose, **do not double the dose**.
- Your healthcare provider will start you on a low dose of ropinirole extended-release tablets. Your healthcare provider will change the dose until you are taking the right amount of medicine to control your symptoms. **It may take several weeks before you reach a dose that controls your symptoms.**
- Contact your healthcare provider if you stop taking ropinirole extended-release tablets for any reason. Do not restart without talking with your healthcare provider.
- Your healthcare provider may prescribe ropinirole extended-release tablets alone, or add ropinirole extended-release tablets to medicine that you are already taking for Parkinson’s disease.
- You should not substitute immediate-release ropinirole tablets for ropinirole extended-release tablets or ropinirole extended-release tablets for immediate-release ropinirole tablets without talking with your healthcare provider.

If you are taking ropinirole extended-release tablets:

- Take ropinirole extended-release tablets 1 time each day for Parkinson’s disease, preferably at or around the same time of day.
- Swallow ropinirole extended-release tablets whole. Do not chew, crush, or split ropinirole extended-release tablets.
- Ropinirole extended-release tablets release drug over a 24-hour period. If you have a condition where medicine passes through your body too quickly, such as diarrhea, the tablet(s) may not dissolve completely and you may see tablet residue in your stool. If this happens, let your healthcare provider know as soon as possible.

What are the possible side effects of ropinirole extended-release tablets?

Ropinirole extended-release tablets can cause serious side effects, including:

- See “**What is the most important information I should know about ropinirole extended-release tablets?**”

The most common side effects of ropinirole extended-release tablets include:

• fainting	• sleepiness or drowsiness	• hallucinations (seeing or hearing things that are not real)	• dizziness
• nausea or vomiting	• uncontrolled sudden movements	• upset stomach, abdominal pain or discomfort	• fatigue, tiredness, or weakness
• confusion	• headache	• leg swelling	• increased sweating
• constipation	• suddenly falling asleep	• high blood pressure (hypertension)	

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all of the possible side effects with ropinirole extended-release tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ropinirole extended-release tablets?

- Store ropinirole extended-release tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep ropinirole extended-release tablets in a tightly closed container and out of direct sunlight.
- Bottles of 30’s, 90’s and 100’s count of ropinirole extended-release tablets come in a child resistant package.

Keep ropinirole extended-release tablets and all medications out of the reach of children.

General information about the safe and effective use of ropinirole extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ropinirole extended-release tablets for a condition for which it was not prescribed. Do not give ropinirole extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ropinirole extended-release tablets that is written for health professionals.

What are the ingredients in ropinirole extended-release tablets?

Active ingredient: ropinirole (as ropinirole hydrochloride)

Inactive ingredients: carboxymethylcellulose sodium, colloidal silicon dioxide, ethylcellulose, hydrogenated castor oil, hypromellose, magnesium stearate, and one or more of the following: FD&C Blue No. 2 aluminum lake, ferric oxides (black, red, yellow), polyethylene glycol 6000, polyethylene glycol 8000, povidone, pregelatinized starch, talc, titanium dioxide.

For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Patient Information Leaflet available at <https://www.alembicusa.com/patientinformationleaflet.aspx> or call 1-866-210-9797.

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