

PATIENT INFORMATION
Ropinirole Tablets USP

If you have Restless Legs Syndrome (RLS, also known as Ekbom Syndrome), read this side

Read this information completely before you start taking ropinirole tablets. Read the information each time you get more medicine. There may be new information. This leaflet provides a summary about ropinirole tablets. It does not include everything there is to know about your medicine. This information should not take the place of discussions with your doctor about your medical condition or ropinirole tablets.

What are ropinirole tablets?

Ropinirole tablets are a prescription medicine to treat moderate-to-severe primary Restless Legs Syndrome. They are sometimes used to treat Parkinson's disease. Having one of these conditions does not mean you have or will develop the other.

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

- Patients with RLS should take ropinirole tablets differently than patients with Parkinson's disease (see **How should I take ropinirole tablets for RLS?** for the recommended dosing for RLS). A lower dose of ropinirole tablets is generally needed for patients with RLS, and is taken once daily before bedtime.
- There are known side effects of ropinirole tablets. If you fall asleep or feel very sleepy while doing normal activities such as driving, faint, feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down, you should talk with your doctor (see **What are the possible side effects of ropinirole tablets?**).
- Before starting ropinirole tablets, be sure to tell your doctor if you are taking any medicines that make you drowsy.

Who should not take ropinirole tablets?

You should not take ropinirole tablets if you are allergic to the active ingredient ropinirole or to any of the inactive ingredients. Your doctor and pharmacist have a list of the inactive ingredients.

What should I tell my doctor?

Be sure to tell your doctor if:

- you are pregnant or plan to become pregnant.
- you are breast-feeding.
- you have daytime sleepiness from a sleep disorder other than RLS or have unexpected sleepiness or periods of sleep while taking ropinirole tablets.
- you are taking any other prescription or over-the-counter medicines. Some of these medicines may increase your chances of getting side effects while taking ropinirole tablets.
- you start or stop taking other medicines while you are taking ropinirole tablets. This may increase your chances of getting side effects.
- you start or stop smoking while you are taking ropinirole tablets. Smoking may decrease the treatment effect of ropinirole tablets.
- you feel dizzy, nauseated, sweaty, or faint when you stand up from sitting or lying down.
- you drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking ropinirole tablets.

How should I take ropinirole tablets for RLS?

- Be sure to take ropinirole tablets exactly as directed by your doctor or healthcare provider.
- The usual way to take ropinirole tablets is once in the evening, 1 to 3 hours before bedtime.
- Your doctor will start you on a low dose of ropinirole tablets. Your doctor may change the dose until you are taking the amount of medicine that is right for you to control your symptoms.
- You may receive a starting kit with doses marked by day. The pills in this kit slowly increase your daily dose over time so that you and your doctor may determine what the best dose is for you. Different people respond differently to this medicine. You may not need the highest dose pill in this kit or you may need an even higher dose to relieve your symptoms. You should carefully follow your doctor's advice on the use of this kit.
- **If you miss your dose, do not double your next dose.** Take only your usual dose 1 to 3 hours before your next bedtime.
- Contact your doctor, if you stop taking ropinirole tablets for any reason. Do not restart without consulting your doctor.
- You can take ropinirole tablets with or without food. Taking ropinirole tablets with food may decrease the chances of feeling nauseated.

What are the possible side effects of ropinirole tablets?

- Most people who take ropinirole tablets tolerate it well. The most commonly reported side effects in people taking ropinirole tablets for RLS are nausea, vomiting, dizziness, and drowsiness or sleepiness. You should be careful until you know if ropinirole tablets affect your ability to remain alert while doing normal daily activities, and you should watch for the development of significant daytime sleepiness or episodes of falling asleep. It is possible that you could fall asleep while doing normal

activities such as driving a car, doing physical tasks, or using hazardous machinery while taking ropinirole tablets. Your chances of falling asleep while doing normal activities while taking ropinirole tablets are greater if you are taking other medicines that cause drowsiness.

- When you start taking ropinirole tablets or when you increase your dose, you may feel dizzy, nauseated, sweaty or faint, when first standing up from sitting or lying down. Therefore, do not stand up quickly after sitting or lying down, particularly if you have been sitting or lying down for a long period of time. Take a minute sitting on the edge of the bed or chair before you get up.
- Some patients taking ropinirole have shown urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble or increased sexual urges and/or behaviors. If you or your family notices that you are developing any unusual behaviors, talk to your doctor.
- Hallucinations (unreal sounds, visions, or sensations) have been reported in patients taking ropinirole tablets. These were uncommon in patients taking ropinirole tablets for RLS. The risk is greater in patients with Parkinson's disease who are elderly, taking ropinirole tablets with L-dopa, or taking higher doses of ropinirole tablets than recommended for RLS.

This is not a complete list of side effects and should not take the place of discussions with your healthcare providers. Your doctor or pharmacist can give you a more complete list of possible side effects. Talk to your doctor about any side effects or problems you may have.

Other Information about ropinirole tablets

- Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the medicines used to treat Parkinson's disease. Ropinirole tablets is one of the medicines used to treat Parkinson's disease, therefore, patients being treated with ropinirole tablets should have periodic skin examinations.
- Take ropinirole tablets exactly as your doctor prescribes it.
- Do not share ropinirole tablets with other people, even if they have the same symptoms you have.
- Keep ropinirole tablets out of the reach of children.
- Store ropinirole tablets at room temperature out of direct sunlight.
- Keep ropinirole tablets in a tightly closed container.

This leaflet summarizes important information about ropinirole tablets. Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not take ropinirole tablets for a condition for which it was not prescribed. For more information, talk with your doctor or pharmacist. They can give you information about ropinirole tablets that is written for healthcare professionals.

Manufactured by:
Glenmark Generics Ltd.
Colvale-Bardez, Goa 403 513, India

Manufactured for:


Glenmark
Glenmark Generics Inc., USA
Mahwah, NJ 07430

Questions? 1 (888)721-7115
www.glenmarkgenerics.com

August 2011

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If you have Parkinson's disease, read this side

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What are ropinirole tablets?

Ropinirole tablets are a prescription medicine used to treat Parkinson's disease. They are also used to treat moderate-to-severe primary Restless Legs Syndrome. Having one of these conditions does not mean you have or will develop the other.

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

- Patients with Parkinson's disease should take ropinirole tablets differently than patients with Restless Legs Syndrome (see **How should I take ropinirole tablets for Parkinson's disease?**) For Parkinson's disease, a higher dose of ropinirole tablets is generally needed, and is taken more frequently throughout the day.
- There are known side effects of ropinirole tablets (see **What are the possible side effects of ropinirole tablets?**)
- If you fall asleep or feel very sleepy while doing normal activities such as driving, faint, feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down, you should talk with your doctor.
- Hallucinations (unreal visions, sounds, or sensations) have been reported in patients taking ropinirole tablets. The risk is greater in patients with Parkinson's disease who are elderly, taking ropinirole tablets with L-dopa or taking higher doses of ropinirole tablets. If these occur, you should discuss them with your doctor.
- Ropinirole tablets may make some of the side effects of L-dopa worse. Ropinirole tablets may cause uncontrolled sudden movements or make such movements you already have worse or more frequent. You should notify your doctor in such a case as dosage adjustments to your anti-Parkinson's medications may be necessary.
- Before starting ropinirole tablets, be sure to tell your doctor if you are taking any medicines that make you drowsy.

Who should not take ropinirole tablets?

You should not take ropinirole tablets if you are allergic to the active ingredient ropinirole or to any of the inactive ingredients. Your doctor and pharmacist have a list of the inactive ingredients.

What should I tell my doctor?

Be sure to tell your doctor if:

- you are pregnant or plan to become pregnant.
- you are breast-feeding.
- you have daytime sleepiness from a sleep disorder or have unexpected sleepiness or periods of sleep while taking ropinirole tablets.
- you are taking any other prescription or over-the-counter medicines. Some of these medicines may increase your chances of getting side effects while taking ropinirole tablets.
- you start or stop taking other medicines while you are taking ropinirole tablets. This may increase your chances of getting side effects.
- you start or stop smoking while you are taking ropinirole tablets. Smoking may decrease the treatment effect of ropinirole tablets.
- you feel dizzy, nauseated, sweaty, or faint when you first stand up from sitting or lying down.
- you drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking ropinirole tablets.

How should I take ropinirole tablets for Parkinson's disease?

- Be sure to take your ropinirole tablets exactly as directed by your doctor or healthcare provider.
- Three times a day is the usual way to take ropinirole tablets for Parkinson's disease.
- Your doctor will start you on a low dose of ropinirole tablets. Your doctor 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.
- **If you miss a dose, do not double your next dose.**
- Contact your doctor, if you stop taking ropinirole tablets for any reason. Do not restart without consulting your doctor.
- Your doctor may prescribe ropinirole tablets alone or add ropinirole tablets to medicine that you are already taking for Parkinson's disease.
- You can take ropinirole tablets with or without food. Taking ropinirole tablets with food may decrease the chances of feeling nauseated.

What are the possible side effects of ropinirole tablets?

- Most people who take ropinirole tablets tolerate it well. The most commonly reported side effects in people taking ropinirole tablets are nausea, headache, dizziness, drowsiness or sleepiness.

- You should be careful until you know if ropinirole tablets affect your ability to remain alert while doing normal daily activities, and you should watch for the development of significant daytime sleepiness or episodes of falling asleep. It is possible that you could fall asleep while doing normal activities such as driving a car, doing physical tasks, or using hazardous machinery while taking ropinirole tablets. Your chances of falling asleep while doing normal activities while taking ropinirole tablets are greater if you are taking other medicines that cause drowsiness.
- When you start taking ropinirole tablets or when you increase your dose, you may feel dizzy, nauseated, sweaty or faint, when first standing up from sitting or lying down. Therefore, do not stand up quickly after sitting or lying down, particularly if you have been sitting or lying down for a long period of time. Take a minute sitting on the edge of the bed or chair before you get up.
- Some patients taking ropinirole have shown urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble or increased sexual urges and/or behaviors. If you or your family notices that you are developing any unusual behaviors, talk to your doctor.
- Hallucinations (unreal visions, sounds, or sensations) have been reported in patients taking ropinirole tablets. The risk is greater in patients with Parkinson's disease who are elderly, taking ropinirole tablets with L-dopa, or taking higher amounts of ropinirole tablets.
- If you are taking L-dopa for Parkinson's disease, ropinirole tablets may make some of the side effects of L-dopa worse. Ropinirole tablets may cause uncontrolled sudden movements or make such movements you already have worse or more frequent.

This is not a complete list of side effects and should not take the place of discussions with your healthcare providers. Your doctor or pharmacist can give you a more complete list of possible side effects. Talk to your doctor about any side effects or problems you may have.

Other Information about ropinirole tablets

- Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the medicines used to treat Parkinson's disease. Therefore, patients being treated with ropinirole tablets should have periodic skin examinations.
- Take ropinirole tablets exactly as your doctor prescribes it.
- Do not share ropinirole tablets with other people, even if they have the same symptoms you have.
- Keep ropinirole tablets out of the reach of children.
- Store ropinirole tablets at room temperature out of direct sunlight.
- Keep ropinirole tablets in a tightly closed container.

This leaflet summarizes important information about ropinirole tablets. Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not take ropinirole tablets for a condition for which it was not prescribed. For more information, talk with your doctor or pharmacist. They can give you information about ropinirole tablets that is written for healthcare professionals.

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