

PATIENT INFORMATION
REQUIP® (RE-qwip) (ropinirole) Tablets

IF YOU HAVE RESTLESS LEGS SYNDROME (RLS), READ THIS SIDE
IF YOU HAVE PARKINSON'S DISEASE, READ THE OTHER SIDE

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

Patients with RLS should take REQUIP differently than patients with Parkinson's disease (see **How should I take REQUIP for RLS?** for the recommended dosing for RLS). A lower dose of REQUIP is generally needed for patients with RLS, and is taken once daily before bedtime.

What is the most important information I should know about REQUIP?

REQUIP 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 REQUIP. 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 REQUIP are greater if you take other medicines that cause drowsiness. Tell your healthcare provider right away if this happens. Before starting REQUIP, be sure to tell your healthcare provider if you take any medicines that make you drowsy.
- **Decrease in blood pressure.** REQUIP can decrease your blood pressure. Lowering of your blood pressure is of special concern. If you faint, feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down, this may mean that your blood pressure is decreased. If you notice this, you should contact your healthcare provider. Also, when changing position from lying down or sitting to standing up, you should do it carefully and slowly. Lowering of your blood pressure can happen especially when you start taking REQUIP or when your dose is increased.
- **Fainting.** Fainting can occur, and sometimes your heart rate may be decreased. This can happen especially when you start taking REQUIP or your dose is increased. Tell your healthcare provider if you faint or feel dizzy.
- **Hallucinations** (unreal visions, sounds, or sensations) can occur in patients taking REQUIP. If you have hallucinations, talk with your healthcare provider.

Unusual urges. Some patients taking REQUIP get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble or increased sexual urges and behaviors. If you notice or your family notices that you are developing any unusual behaviors, talk to your healthcare provider.

See “What are the possible side effects of REQUIP?”

What is REQUIP?

REQUIP is a prescription medicine containing ropinirole used to treat moderate-to-severe primary Restless Legs Syndrome. It is also used to treat Parkinson's disease. Having one of these conditions does not mean you have or will develop the other.

REQUIP has not been studied in children.

What should I tell my healthcare provider before taking REQUIP?

Be sure to tell your healthcare provider if you:

- have daytime sleepiness from a sleep disorder or have unexpected or unpredictable sleepiness or periods of sleep.
- are taking any other prescription or over-the-counter medicines. Some of these medicines may increase your chances of getting side effects while taking REQUIP.
- start or stop taking other medicines while you are taking REQUIP. This may increase your chances of getting side effects.
- start or stop smoking while you are taking REQUIP. Smoking may decrease the treatment effect of REQUIP.
- feel dizzy, nauseated, sweaty, or faint when you first stand up from sitting or lying down.
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking REQUIP.
- have high or low blood pressure.
- are pregnant or plan to become pregnant. REQUIP should only be used during pregnancy if needed.
- are breastfeeding. It is not known if REQUIP passes into your breast milk. Talk to your healthcare provider to decide whether you will breastfeed or take REQUIP.
- are allergic to any of the ingredients in REQUIP. See the end of this Patient Information leaflet for a complete list of the ingredients in REQUIP.

How should I take REQUIP for RLS?

- Take REQUIP exactly as directed by your healthcare provider.
- The usual way to take REQUIP is once in the evening, 1 to 3 hours before bedtime.
- Your healthcare provider will start you on a low dose of REQUIP. Your healthcare provider may change the dose until you are taking the right amount of medicine to control your symptoms.

- **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 healthcare provider if you stop taking REQUIP for any reason. Do not restart without consulting your healthcare provider.
- You can take REQUIP with or without food. Taking REQUIP with food may decrease the chances of feeling nauseated.

What are the possible side effects of REQUIP?

Serious side effects in people taking REQUIP are described in the section “REQUIP can cause serious side effects including” and include:

- Falling asleep during normal activities
- Decrease in blood pressure
- Fainting
- Hallucinations

Some patients taking REQUIP get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble or increased sexual urges and behaviors. If you notice or your family notices that you are developing any unusual behaviors, talk to your healthcare provider.

You should be careful until you know if REQUIP affects your ability to remain alert while doing normal daily activities, driving a car, operating machinery, or working at heights. You should also watch for the development of significant daytime sleepiness or episodes of falling asleep.

Common side effects in people taking REQUIP include:

- Nausea or vomiting
- Sleepiness or drowsiness
- Dizziness
- Fatigue

This is not a complete list of side effects and should not take the place of discussions with your healthcare providers. Your healthcare provider or pharmacist can give you a more complete list of possible side effects.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REQUIP?

- Store REQUIP Tablets between 68°-77°F (20°-25°C).
- Store REQUIP at room temperature out of direct sunlight.
- Keep REQUIP in a tightly closed container.

- Keep REQUIP out of the reach of children.

Other Information about REQUIP

- Do not share REQUIP with other people, even if they have the same symptoms you have.
- 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. REQUIP is one of the medicines used to treat Parkinson's disease, therefore, patients being treated with REQUIP should have periodic skin examinations.

This patient information leaflet summarizes important information about REQUIP for Restless Legs Syndrome. Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not take REQUIP for a condition for which it was not prescribed. For more information, talk with your healthcare provider or pharmacist. They can give you information about REQUIP that is written for healthcare professionals. For more information call 1-888-825-5249 (toll-free) or visit www.requip.com.

What are the ingredients in REQUIP?

The following ingredients are in REQUIP:

Active ingredient: ropinirole (as ropinirole hydrochloride)

Inactive ingredients: croscarmellose sodium, hydrous lactose, magnesium stearate, microcrystalline cellulose, and one or more of the following: carmine, FD&C Blue No.2 aluminum lake, FD&C Yellow No. 6 aluminum lake, hypromellose, iron oxides, polyethylene glycol, polysorbate 80, titanium dioxide.

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