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**PHARMACIST--DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT**

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**PATIENT INFORMATION**

**REQUIP® (RE-qwip) (ropinirole) Tablets**

**REQUIP® XL™ (RE-qwip)**

**(ropinirole extended-release tablets)**

**IF YOU HAVE PARKINSON'S DISEASE, READ THIS SIDE**

**IF YOU HAVE RESTLESS LEGS SYNDROME, READ THE OTHER SIDE**

**IMPORTANT NOTE: REQUIP XL has not been studied in Restless Legs Syndrome (RLS) and is not approved for the treatment of RLS. However, an immediate-release form of ropinirole (REQUIP) is approved for the treatment of RLS (see other side of this leaflet).**

**Read this information completely before you start taking REQUIP or REQUIP XL.** Read the information each time you get more medicine. There may be new information. This leaflet provides a summary about REQUIP and REQUIP XL. 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 or REQUIP XL.

**What are REQUIP and REQUIP XL?**

REQUIP is a short-acting prescription medicine containing ropinirole (usually taken 3 times a day) used to treat Parkinson's disease. It is also used to treat a condition called Restless Legs Syndrome.

REQUIP XL is a long-acting prescription medicine containing ropinirole (taken once a day) used to treat Parkinson's disease.

You should not be taking more than one medicine containing ropinirole. Inform your physician if you are taking any other medicine containing ropinirole.

REQUIP and REQUIP XL have not been studied in children.

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

**REQUIP and REQUIP XL 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 or REQUIP XL. 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 or REQUIP XL are greater if you take other medicines that cause drowsiness. Tell your healthcare provider right away if this happens. Before starting REQUIP or REQUIP XL, be sure to tell your healthcare provider if you take any medicines that make you drowsy.

- **Changes in blood pressure.** REQUIP and REQUIP XL can decrease or increase 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 REQUIP XL 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 REQUIP XL 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 or REQUIP XL. The chances of having hallucinations are higher in patients with Parkinson's disease who are elderly, taking REQUIP or REQUIP XL with other Parkinson's disease drugs, or taking higher doses of REQUIP or REQUIP XL. If you have hallucinations, talk with your healthcare provider.
- **Uncontrolled sudden movements.** REQUIP or REQUIP XL 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 REQUIP or REQUIP XL 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 and REQUIP XL?”**

### **What should I tell my healthcare provider before taking REQUIP or REQUIP XL?**

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 or REQUIP XL.
- start or stop taking other medicines while you are taking REQUIP or REQUIP XL. This may increase your chances of getting side effects.

- start or stop smoking while you are taking REQUIP or REQUIP XL. Smoking may decrease the treatment effect of REQUIP or REQUIP XL.
- 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 or REQUIP XL.
- have high or low blood pressure.
- are pregnant or plan to become pregnant. REQUIP and REQUIP XL should only be used during pregnancy if needed.
- are breastfeeding. It is not known if REQUIP or REQUIP XL passes into your breast milk. Talk to your healthcare provider to decide whether you will breastfeed or take REQUIP or REQUIP XL.
- are allergic to any of the ingredients in REQUIP or REQUIP XL. See the end of this Patient Information leaflet for a complete list of the ingredients in REQUIP and REQUIP XL.

### **How should I take REQUIP or REQUIP XL for Parkinson's disease?**

- Take REQUIP or REQUIP XL exactly as directed by your healthcare provider.
- Do not suddenly stop taking REQUIP or REQUIP XL without talking to your healthcare provider. If you stop this medicine suddenly, you may develop fever, confusion, or severe muscle stiffness.
- Before starting REQUIP or REQUIP XL, 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 REQUIP or REQUIP XL. 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.**

### **If you are taking REQUIP:**

- REQUIP Tablets are usually taken 3 times each day for Parkinson's disease.

### **If you are taking REQUIP XL:**

- Take REQUIP XL Tablets 1 time each day for Parkinson's disease, preferably at or around the same time of day.
- Swallow REQUIP XL Tablets whole. Do not chew, crush, or split REQUIP XL Tablets.

### **If you are taking either REQUIP or REQUIP XL:**

- Contact your healthcare provider if you stop taking REQUIP or REQUIP XL for any reason. Do not restart without talking with your healthcare provider.
- Your healthcare provider may prescribe REQUIP or REQUIP XL alone, or add REQUIP or REQUIP XL to medicine that you are already taking for Parkinson's disease.

- You should not substitute REQUIP for REQUIP XL or REQUIP XL for REQUIP without talking with your healthcare provider.
- You can take REQUIP or REQUIP XL with or without food. If you experience nausea you may try taking REQUIP or REQUIP XL with food.

### **What are the possible side effects of REQUIP and REQUIP XL?**

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

- Falling asleep during normal activities
- Changes in blood pressure
- Fainting
- Hallucinations
- Uncontrolled sudden movements

Some patients taking REQUIP or REQUIP XL 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 or REQUIP XL 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 and REQUIP XL include:

- Fainting
- Sleepiness
- Hallucinations
- Dizziness
- Nausea or vomiting
- Uncontrolled sudden movements
- Leg swelling
- Fatigue
- Headache
- Upset stomach
- Increased sweating

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 and REQUIP XL?**

- Store REQUIP Tablets between 68°-77°F (20°-25°C).
- Store REQUIP XL Tablets between 59°-86°F (15°-30°C).
- Store REQUIP or REQUIP XL at room temperature out of direct sunlight.
- Keep REQUIP or REQUIP XL in a tightly closed container.
- Keep REQUIP or REQUIP XL out of the reach of children.

### **Other Information about REQUIP and REQUIP XL:**

- Do not share REQUIP or REQUIP XL 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 and REQUIP XL are two of the medicines used to treat Parkinson's disease, therefore, patients being treated with REQUIP or REQUIP XL should have periodic skin examinations.

This patient information leaflet summarizes the most important information about REQUIP and REQUIP XL for Parkinson's disease. Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not take REQUIP or REQUIP XL 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 and REQUIP XL that is written for healthcare professionals. For more information call 1-888-825-5249 (toll-free) or visit [www.requipxl.com](http://www.requipxl.com).

### **What are the ingredients in REQUIP and REQUIP XL?**

#### **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.

#### **The following ingredients are in REQUIP XL:**

**Active ingredient:** ropinirole (as ropinirole hydrochloride)

**Inactive ingredients:** carboxymethylcellulose sodium, colloidal silicon dioxide, glycerol behenate, hydrogenated castor oil, hypromellose, lactose monohydrate, magnesium stearate,

maltodextrin, mannitol, povidone, and one or more of the following: FD&C Yellow No. 6 aluminum lake, FD&C Blue No. 2 aluminum lake, ferric oxides (black, red, yellow), polyethylene glycol 400, titanium dioxide.