

## PATIENT INFORMATION

# Ropinirole (roe PIN i role) Tablets USP

If you have Parkinson's disease, read this side. If you have Restless Legs Syndrome (RLS), read the other side.

**Important Note:** An immediate-release form of ropinirole is approved for the treatment of moderate to severe primary RLS (see other side of this leaflet).

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 healthcare provider about your medical condition or treatment with ropinirole tablets.

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

#### Ropinirole tablets can cause serious side effects, including:

- **Hypersensitivity/allergic reactions.** You may experience a hypersensitivity/allergic reaction characterized by hives, rash, itching, and/or swelling of the face, lips, mouth, tongue, or throat, which may cause problems in swallowing or breathing. **If you experience any of these reactions**, you should not take ropinirole tablets again until you talk to a healthcare provider and seek their advice.
- **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 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 tablets are greater if you take other medicines that cause drowsiness. Tell your healthcare provider right away if this happens. Before starting ropinirole 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 tablets or your dose is increased. Tell your healthcare provider if you faint or feel dizzy or light-headed.
- **Decrease in blood pressure.** Ropinirole tablets can decrease your blood pressure. Decreases in your blood pressure (hypotension) can happen, especially when you start taking ropinirole 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.
- **Changes in heart rate (decrease or increase).** Ropinirole tablets can decrease or increase your heart rate.
- **Hallucinations and other psychotic-like behavior.** Ropinirole 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 tablets 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 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 medicine may need to be changed.
- **Unusual urges.** Some patients taking ropinirole 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.
- **Increased chance of skin cancer (melanoma).** People with Parkinson's disease may have a higher chance of getting melanoma. It is not known if ropinirole tablets increase your chances of getting melanoma. You and your healthcare provider should check your skin on a regular basis. Tell your healthcare provider right away if you notice any changes in your skin such as a change in the size, shape, or color of moles on your skin.

### What is ropinirole tablet?

- Ropinirole tablets are a short-acting prescription medicine containing ropinirole (usually taken 3 times a day) that is used to treat Parkinson's disease. It is also used to treat a condition called 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 tablets are safe and effective for use in children younger than 18 years of age.

### Who should not take ropinirole tablets?

#### Do not take ropinirole tablet if you:

- are allergic to ropinirole or any of the ingredients in ropinirole tablets. See the end of this page for a complete list of the ingredients in ropinirole tablets.

**Call your healthcare provider and get help right away if you have any of the following symptoms of an allergic reaction. Symptoms of an allergic reaction may include:**

- hives
- rash
- swelling of the face, lips, mouth, tongue, or throat
- itching

### What should I tell my healthcare provider before taking ropinirole tablets?

#### Before you take ropinirole tablet, 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 ropinirole tablets.
- start or stop taking other medicines while you are taking ropinirole tablets. This may increase your chances of getting side effects.
- start or stop smoking while you are taking ropinirole tablets. Smoking may decrease the treatment effect of ropinirole 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 tablets.
- have high or low blood pressure.
- have or have had heart problems.

- are pregnant or plan to become pregnant. Ropinirole tablets may harm your unborn baby. Ropinirole tablets should only be used during pregnancy if needed.
- are breastfeeding or plan to breastfeed. It is not known if ropinirole passes into your breast milk, and the amount of breast milk you produce may be decreased while taking ropinirole tablets. You and your healthcare provider should decide if you should take ropinirole tablets while breastfeeding.
- have any other medical conditions.

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

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

#### **If you are taking ropinirole tablets:**

- Ropinirole tablets are usually taken 3 times a day for Parkinson's disease.

#### **If you are taking ropinirole tablets:**

- Contact your healthcare provider if you stop taking ropinirole tablets for any reason. Do not restart without talking with your healthcare provider.
- Your healthcare provider 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.

#### **What are the possible side effects of ropinirole tablets?**

##### **Ropinirole tablets can cause serious side effects, including:**

- **See "What is the most important information I should know about ropinirole tablets?"**

The most common side effects of ropinirole tablets include:

- fainting
- sleepiness or drowsiness
- hallucinations (seeing or hearing things that are not real)
- dizziness
- nausea or vomiting
- uncontrolled sudden movements
- leg swelling
- fatigue, tiredness, or weakness
- confusion
- headache
- upset stomach, abdominal pain or discomfort
- increased sweating

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

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

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 tablets?**

- Store ropinirole tablets at controlled room temperature 20° to 25°C (68° to 77°F), [See USP]. Protect from light and moisture.

#### **Keep ropinirole tablets and all medicines out of the reach of children.**

#### **General information about the safe and effective use of ropinirole tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. do not take ropinirole tablets for a condition for which it was not prescribed. Do not give ropinirole tablets to other people, even if they have the same symptoms you have. It may harm them.

This side of the patient information leaflet summarizes the most important information about ropinirole tablets for parkinson's disease. If you would like more information, talk with your healthcare provider or pharmacist. you can ask your healthcare provider or pharmacist for information about ropinirole tablets that is written for healthcare professionals. For more information call Alembic Pharmaceuticals Limited at 1-866 210 9797.

#### **What is the ingredients in ropinirole tablet?**

##### **The following ingredients are in ropinirole tablets:**

**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.

Manufactured by:

##### **Alembic Pharmaceuticals Limited**

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

##### **Alembic Pharmaceuticals, Inc.**

750 Route 202, Bridgewater, NJ 08807 USA

PHARMACIST DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

Revised: 02/2017

## PATIENT INFORMATION

# Ropinirole (roe PIN i role) Tablets USP

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 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 healthcare provider about your medical condition or treatment with ropinirole tablets.

People with RLS should take ropinirole tablets differently than people with parkinson's disease (see "How should I take ropinirole tablets for RLS?" for the recommended dosing for rls). a lower dose is generally needed for people with RLS, and is taken once daily before bedtime.

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

**Ropinirole tablets can cause serious side effects, including:**

- **Hypersensitivity/allergic reactions.** You may experience a hypersensitivity/allergic reaction characterized by hives, rash, itching, and/or swelling of the face, lips, mouth, tongue, or throat, which may cause problems in swallowing or breathing. **If you experience any of these reactions** after starting ropinirole tablets, you should not take ropinirole tablets again until you talk to a healthcare provider and seek their advice.
- **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 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 tablets are greater if you take other medicines that cause drowsiness. tell your healthcare provider right away if this happens. Before starting ropinirole tablets, be sure to tell your healthcare provider if you take any medicines that make you drowsy.
- **Fainting.** fainting can occur, and sometimes your heart rate may be decreased. this can happen especially when you start taking ropinirole tablets or your dose is increased. tell your healthcare provider if you faint or feel dizzy or light-headed.
- **Decrease in blood pressure.** Ropinirole tablet can decrease your blood pressure (hypotension), especially when you start taking ropinirole tablet or when your dose is changed. If you feel 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.
- **Changes in heart rate (decrease or increase).** Ropinirole tablets can decrease or increase your heart rate.
- **Unusual urges.** Some patients taking ropinirole 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.
- **Increased chance of skin cancer (melanoma).** It is not known if ropinirole tablets increases your chance of getting melanoma. You and your healthcare provider should check your skin on a regular basis. Tell your healthcare provider right away if you notice any changes in your skin such as a change in the size, shape, or color of moles on your skin.
- **Changes in restless legs syndrome symptoms.** Ropinirole tablets may cause restless legs symptoms to come back in the morning (rebound), happen earlier in the evening, or even happen in the afternoon.

**What is ropinirole tablet?**

Ropinirole tablet is a prescription medicine containing ropinirole used to treat moderate-to-severe primary Restless Legs Syndrome (RLS). It is also used to treat Parkinson's disease.

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 tablet is safe and effective for use in children younger than 18 years of age.

**Who should not take ropinirole tablets?**

**Do not take ropinirole tablets if you:**

- are allergic to ropinirole or any of the ingredients in ropinirole tablet. See the end of this leaflet for a complete list of the ingredients in ropinirole tablet.

**Call your healthcare provider and get help right away if you have any of the following symptoms of an allergic reaction. Symptoms of an allergic reaction may include:**

- hives
- rash
- swelling of the face, lips, mouth, tongue, or throat
- itching

**What should I tell my healthcare provider before taking ropinirole tablets?**

**Before you take ropinirole tablet, 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 ropinirole tablets.
- start or stop taking other medicines while you are taking ropinirole tablets. This may increase your chances of getting side effects.
- start or stop smoking while you are taking ropinirole tablets. smoking may decrease the treatment effect of ropinirole 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 tablets.
- have high or low blood pressure.

- have or have had heart problems.
- are pregnant or plan to become pregnant. Ropinirole tablets may harm your unborn baby. Ropinirole tablets should only be used during pregnancy if needed.
- are breastfeeding or plan to breastfeed. It is not known if ropinirole passes into your breast milk, and the amount of breast milk you produce may be decreased while taking ropinirole tablets. You and your healthcare provider should decide if you should take ropinirole tablets while breastfeeding.
- have any other medical conditions.

#### **How should I take ropinirole tablets for RLS?**

- Take ropinirole tablets exactly as directed by your healthcare provider.
- The usual way to take ropinirole tablets is once in the evening, 1 to 3 hours before bedtime.
- Your healthcare provider will start you on a low dose of ropinirole tablets. 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 before you stop taking ropinirole tablets for any reason. Do not restart without consulting your healthcare provider.
- You can take ropinirole tablets with or without food.

#### **What are the possible side effects of ropinirole tablets?**

##### **Ropinirole tablets can cause serious side effects, including:**

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

The most common side effects of ropinirole tablets include:

- nausea or vomiting
- drowsiness or sleepiness
- dizziness
- fatigue, tiredness, or weakness

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

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

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 tablets?**

- Store ropinirole tablets at controlled room temperature 20° to 25°C (68° to 77°F), [See USP]. Protect from light and moisture.

#### **Keep ropinirole tablets and all medicines out of the reach of children.**

#### **General information about the safe and effective use of ropinirole tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not take ropinirole tablets for a condition for which it was not prescribed. Do not give ropinirole tablets to other people, even if they have the same symptoms you have. It may harm them.

This side of the patient information leaflet summarizes the most important information about ropinirole tablets for restless legs syndrome (RLS). If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about ropinirole tablets that is written for healthcare professionals. For more information call Alembic Pharmaceuticals Limited at 1-866 210 9797.

#### **What are the ingredients in ropinirole tablets ?**

**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.

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

Manufactured by:

**Alembic Pharmaceuticals Limited**

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

**Alembic Pharmaceuticals, Inc.**

750 Route 202, Bridgewater, NJ 08807

USA

Revised: 02/2017