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).

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

Ropinirole 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 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, feel dizzy, or feel light-headed.
- **Decrease in blood pressure.** Ropinirole tablets can decrease your blood pressure (hypotension) 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 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 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.
- **Withdrawal Symptoms.** Ropinirole tablets and are dopamine agonist medicines. Dopamine agonist medicines, including ropinirole tablets can cause withdrawal symptoms as your dose is slowly lowered (tapered) or when treatment with ropinirole tablets is stopped. Tell your doctor right away if you get any of the following withdrawal symptoms:
  - o fever
  - o confusion
  - o severe muscle stiffness
  - o insomnia
  - o depression
  - o anxiety
  - o fatigue
  - o sweating
  - o pain
  - o feeling like you do not care about things you usually care about (apathy)

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

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.

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.

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 tablet, 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 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. It is not known if ropinirole 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 tablets. Talk to your healthcare provider to decide if you should breastfeed while taking ropinirole 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 tablets.

How should I take ropinirole tablets?

- Take ropinirole tablets exactly as directed by your healthcare provider.
- Take ropinirole tablets with or without food.
- **Do not** suddenly stop taking ropinirole 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 tablets?**").
- 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.**
- 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 should not substitute ropinirole tablets for ropinirole extended release tablets or ropinirole extended release tablets for ropinirole tablets without talking with your healthcare provider.

If you are taking ropinirole tablets:

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

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
- 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 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 tablets?

- Store ropinirole tablet at controlled room temperature 20° to 25°C (68° to 77°F), [See USP].
- Keep ropinirole tablets in a tightly closed container and out of direct sunlight.
- Ropinirole tablets come in a child-resistant package.

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 use 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 that you have. It may harm them.

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

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

What are the ingredients in ropinirole tablets?

The following ingredients are in ropinirole tablets:

Active ingredient: ropinirole (as ropinirole hydrochloride)

Inactive ingredients: croscarmellose sodium, lactose monohydrate, 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 (iron oxide black, iron oxide red and iron oxide yellow) polyethylene glycol, polysorbate 80 and titanium dioxide.

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.

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 of ropinirole tablet is generally needed for people with RLS, and is taken once daily before bedtime.

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Ropinirole 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 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, feel dizzy, or feel 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 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.
- **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. If you have hallucinations or any of these other psychotic-like changes, talk with your healthcare provider.
- **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.
- **Withdrawal Symptoms.** Ropinirole tablets and are dopamine agonist medicines. Dopamine agonist medicines, including ropinirole tablets can cause withdrawal symptoms as your dose is slowly lowered (tapered) or when treatment with ropinirole tablets is stopped. Tell your doctor right away if you get any of the following withdrawal symptoms:
  - o fever
  - o confusion
  - o severe muscle stiffness
  - o insomnia
  - o depression
  - o anxiety
  - o fatigue
  - o sweating
  - o pain
  - o feeling like you do not care about things you usually care about (apathy)

  After you have stopped taking ropinirole tablets, your healthcare provider may need to restart you at a low dose of ropinirole tablets if you get severe withdrawal symptoms.
- **Changes in RLS symptoms.** Ropinirole tablets may cause RLS 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 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.

Do not take ropinirole tablet if you:

- are allergic to ropinirole or any of the ingredients in ropinirole tablet. See the end of this page for a complete list of the ingredients in ropinirole tablet.
- 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 tablet, 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 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. It is not known if ropinirole 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 tablets. Talk to your healthcare provider to decide if you should breastfeed while taking ropinirole 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 tablets.

How should I take ropinirole tablets?

- Take ropinirole tablets exactly as directed by your healthcare provider.
- Ropinirole tablets are usually taken once in the evening, 1 to 3 hours before bedtime.
- Take ropinirole tablets with or without food.
- **Do not** suddenly stop taking ropinirole 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 tablets?**").
- 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 if you stop taking ropinirole tablets for any reason. Do not restart without talking with your healthcare provider.

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

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

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What are the ingredients in ropinirole tablets?

Active ingredient: ropinirole (as ropinirole hydrochloride)

Inactive ingredients: croscarmellose sodium, lactose monohydrate, 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 (iron oxide black, iron oxide red and iron oxide yellow) polyethylene glycol, polysorbate 80 and titanium dioxide.

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