

If you are being treated for moderate to severe primary Restless Legs Syndrome (RLS), this message is for you.

Getting the most from MIRAPEX

- ➔ It's important to take your MIRAPEX as your healthcare professional prescribed it. MIRAPEX works best if taken daily.
- ➔ MIRAPEX should be taken **once a day, 2 to 3 hours before bedtime.**

Lifestyle tips

Here are simple techniques that can work hand in hand with MIRAPEX to ease RLS symptoms:

- TIP ➤ Cut down on or eliminate caffeine, alcohol and smoking.
- TIP ➤ Stretch your legs by taking a stroll
- TIP ➤ Keep your mind busy with a puzzle or game
- TIP ➤ Soak in a warm bath, or use a hot compress
- TIP ➤ Give your legs a soothing massage

What to expect from MIRAPEX

- ➔ MIRAPEX can help relieve the frequency & severity of many of the symptoms associated with moderate to severe primary Restless Legs Syndrome (RLS).
- ➔ Side effects are mild and decreased over time. The most common side effects are nausea, headache and tiredness.
- ➔ MIRAPEX is not expected to interact with many commonly prescribed medications. Talk to your healthcare professional about drug-to-drug interactions.



pramipexole hydrochloride tablets

Please see accompanying Patient Information for MIRAPEX.

For a free RLS guide and money saving offer, go to www.MIRAPEX.com/CHC or call 866-Rx4-LEGS (866-794-5347)

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Mirapex®

(pramipexole dihydrochloride)
0.125 mg, 0.25 mg, 0.5 mg,
1 mg, and 1.5 mg Tablets

Patient Information

Mirapex® /mīr'ah-pēx/ (pramipexole dihydrochloride) tablets

Read the Patient Information that comes with MIRAPEX before you start taking it and each time you get a refill. There may be some new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

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

MIRAPEX may cause you to fall asleep while you are doing daily activities such as driving, talking with other people, watching TV, or eating.

- Some people taking MIRAPEX have had car accidents because they fell asleep while driving.
- Some patients did not feel sleepy before they fell asleep while driving. You could fall asleep without any warning.

Do not drive a car, operate a machine, or do anything that needs you to be alert until you know how MIRAPEX affects you.

Tell your doctor right away if you fall asleep while you are doing activities such as talking with people, watching TV, eating, or driving, or if you feel sleepier than is normal for you.

What is MIRAPEX?

MIRAPEX is a prescription medicine to treat

- primary Restless Legs Syndrome.
- signs and symptoms of Parkinson's disease.

MIRAPEX has not been studied in children.

Who should not take MIRAPEX?

Do not take MIRAPEX if you are allergic to pramipexole or any of the inactive ingredients of MIRAPEX. See the end of this leaflet for a complete list of ingredients in MIRAPEX.

What should I tell my doctor before taking MIRAPEX?

- Tell your doctor about all of your medical conditions, including if you**
- feel sleepy during the day from a sleep problem other than Restless Legs Syndrome.
 - have low blood pressure, or if you feel dizzy or faint, especially when getting up from a lying or sitting position.
 - have trouble controlling your muscles (dyskinesia).
 - have kidney problems.
 - are pregnant or plan to become pregnant. It is not known if MIRAPEX will harm your unborn baby.
 - are breast feeding. It is not known if MIRAPEX will pass into your breast milk. You and your doctor should decide if you will take MIRAPEX or breastfeed. You should not do both.
 - drink alcohol. Alcohol can increase the chance that MIRAPEX will make you feel sleepy or fall asleep when you should be awake.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take any other medicines that make you sleepy. Mirapex (pramipexole dihydrochloride) tablets and other medicines may interact with each other causing side effects. MIRAPEX may affect the way other medicines work, and other medicines may affect how MIRAPEX works.

How should I take MIRAPEX?

- Take MIRAPEX exactly as your doctor tells you to. Your doctor will tell you how many MIRAPEX tablets to take and when to take them.
- Your doctor may change your dose until you are taking the right amount of medicine to control your symptoms. Do not take more or less MIRAPEX than your doctor tells you to.
- MIRAPEX can be taken with or without food. Taking MIRAPEX with food may lower your chances of getting nausea.
- If you miss a dose, do not double your next dose. Skip the dose you missed and take your next regular dose.
- Be sure to tell your doctor right away if you stop taking MIRAPEX for any reason. Do not start taking MIRAPEX again before speaking with your doctor. If you have Parkinson's disease and are stopping MIRAPEX, you should stop MIRAPEX slowly over 7 days.

What should I avoid while taking MIRAPEX?

- Do not drive a car, operate a machine, or do anything that needs you to be alert until you know how MIRAPEX affects you. See "What is the most important information I should know about MIRAPEX?" at the beginning of this leaflet.
- Do not drink alcohol while taking MIRAPEX. It can increase your chances of feeling sleepy or falling asleep when you should be awake.

What are the possible side effects of MIRAPEX?

MIRAPEX can cause serious side effects, including

- falling asleep during normal daily activities. See "What is the most important information I should know about MIRAPEX?"
- low blood pressure when you sit or stand up quickly. You may have dizziness, nausea, fainting, or sweating. Sit and stand up slowly after you have been sitting or lying down for a while.
- hallucinations. You may see, hear, feel, or taste something that isn't there. You have a higher chance of having hallucinations if you are over 65 years old.

The most common side effects in people taking MIRAPEX for Restless Legs Syndrome are nausea and sleepiness.

The most common side effects in people taking MIRAPEX for Parkinson's disease are nausea, dizziness, sleepiness, constipation, hallucinations, insomnia, muscle weakness, confusion, and abnormal movements.

These are not all the possible side effects of MIRAPEX. For more information ask your doctor or pharmacist.

Be sure to talk to your doctor about any side effects that bother you or that do not go away.

Other Information about MIRAPEX

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. Mirapex is one of the medicines used to treat Parkinson's disease, therefore, patients being treated with Mirapex should have periodic skin examinations.

There have been reports of patients taking certain medicines to treat Parkinson's disease or RLS, including MIRAPEX, that have reported problems with gambling, compulsive eating, and increased sex drive. It is not possible to reliably estimate how often these behaviors occur or to determine which factors may contribute to them. If you or your family members notice that you are developing unusual behaviors, talk to your doctor.

How should I store Mirapex (pramipexole dihydrochloride) tablets?

- Store MIRAPEX at room temperature at 59°F to 86°F (15°C to 30°C).
- Keep MIRAPEX out of light.
- Keep MIRAPEX and all medicines out of the reach of children.

General information about MIRAPEX

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not take MIRAPEX for a condition for which it was not prescribed. Do not share MIRAPEX with other people, even if they have the same symptoms you do. It may harm them.

This Patient Information leaflet summarizes the most important information about MIRAPEX. For more information, talk with your doctor or pharmacist. They can give you information about MIRAPEX that is written for healthcare professionals. For additional information, you may also call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257, or (TTY) 1-800-459-9906. You may also request information through the company website at <http://us.boehringer-ingelheim.com>.

What are the ingredients in MIRAPEX?

Active Ingredient: pramipexole dihydrochloride monohydrate

Inactive Ingredients: mannitol, corn starch, colloidal silicon dioxide, povidone, and magnesium stearate

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U.S. Patent Nos. 4,886,812; 6,001,861; and 6,194,445.

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What's keeping you up at night?
Are your restless legs to blame?

Restless Legs Syndrome (RLS)
is a real condition, with real
day-to-day consequences

Take this quiz and share your answers with your doctor

- I have a strong urge to move my legs when resting. Yes No
- I have feelings in my legs such as burning, creeping, crawling, aching, tingling, tugging, and itching. These feelings are worse when I rest or lay down. Yes No
- Moving my legs gives me relief. Yes No
- My symptoms are worse at night and when I rest. Yes No

If you said YES to these questions, you may have a treatable condition called Restless Legs Syndrome (RLS).
Talk to your doctor today.

MIRAPEX is indicated for the treatment of moderate to severe primary RLS.

MIRAPEX can help relieve the frequency & severity of many of the symptoms associated with moderate to severe primary RLS, such as the urge to move.

Please see accompanying Patient Information for MIRAPEX.



Talk to your doctor about MIRAPEX
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go to www.MIRAPEX.com/CHC
or call 1-877-RID-RLS1 (1-877-743-7571)

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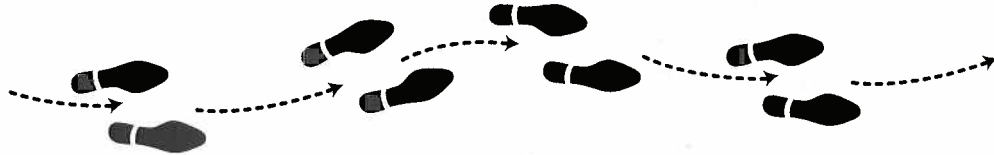
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Which of these patients suffers from RLS?

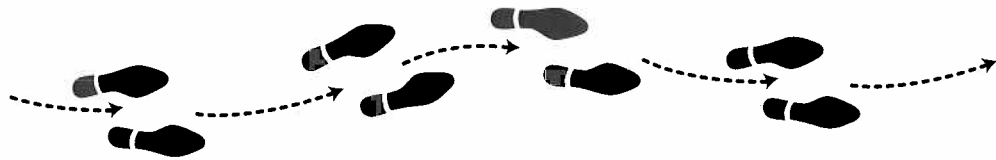


They all do!



RLS affects a range of patients^{1,2}

- RLS is a neurological sensorimotor disorder³
- Up to 10% of the US adult population is affected by mild, moderate, or severe symptoms of RLS, which often goes undiagnosed¹
- Approximately 12 million Americans suffer from moderate to severe primary RLS^{1,2,4}
- The mean age of onset in patients with RLS is 46 years¹
- RLS is more common in women than in men^{1,2}
- RLS can affect people regardless of race/ethnicity²
- 63% of patients with RLS report having at least one first-degree relative with the condition⁵






IMPORTANT SAFETY INFORMATION ABOUT MIRAPEX:

Patients have reported falling asleep without perceived warning signs during activities of daily living, including operation of a motor vehicle. Hallucinations and postural (orthostatic) hypotension may occur. The most commonly reported adverse events in clinical trials for RLS were nausea, headache, fatigue, and somnolence.

Patients and caregivers should be informed that impulse control disorders/compulsive behaviors may occur while taking medicines, including pramipexole, to treat Parkinson's disease and RLS. Please see accompanying full Prescribing Information.



References: 1. Hening W, Walters AS, Allen RP, et al. Impact, diagnosis and treatment of restless legs syndrome (RLS) in a primary care population: the REST (RLS epidemiology, symptoms, and treatment) primary care study. *Sleep Med.* 2004;5:237-246. 2. National Heart Lung and Blood Institute. Diseases and Conditions Index: Restless Legs Syndrome. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/rls/rls_WholsAtRisk.html. Accessed February 27, 2007. 3. Hening W. The clinical neurophysiology of the restless legs syndrome and periodic limb movements. Part I: diagnosis, assessment, and characterization. *Clin Neurophysiol.* 2004;115:1965-1974. 4. US Census Bureau. Table 1: Population Age 18 or Over: July 1, 2003. Available at: <http://www.census.gov/Press-Release/www/releases/CB04-36TABLE1.pdf>. Accessed February 27, 2007. 5. Montplaisir J, Boucher S, Poirier G, et al. Clinical, polysomnographic, and genetic characteristics of restless legs syndrome: a study of 133 patients diagnosed with new standard criteria. *Mov Disord.* 1997;12:61-65.
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