

# Patient Information

## Pramipexole Dihydrochloride Tablets

### 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg Tablets

(Rx Only)

Read the Patient Information that comes with pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets?

**Pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets affect 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 are pramipexole dihydrochloride tablets?

Pramipexole dihydrochloride tablets are a prescription medicine to treat signs and symptoms of Parkinson's disease.

Pramipexole dihydrochloride tablets have not been studied in children.

#### Who should not take pramipexole dihydrochloride tablets?

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

#### What should I tell my doctor before taking pramipexole dihydrochloride tablets?

**Tell your doctor about all of your medical conditions, including if you**

- feel sleepy during the day from a sleep problem.
- 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 pramipexole dihydrochloride tablets will harm your unborn baby.
- are breast feeding. It is not known if pramipexole dihydrochloride tablets will pass into your breast milk. You and your doctor should decide if you will take pramipexole dihydrochloride tablets or breast feed. You should not do both.
- drink alcohol. Alcohol can increase the chance that pramipexole dihydrochloride tablets 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.** Pramipexole dihydrochloride tablets and other medicines may interact with each other causing side effects. Pramipexole dihydrochloride tablets may affect the way other medicines work, and other medicines may affect how pramipexole dihydrochloride tablets work.

#### How should I take pramipexole dihydrochloride tablets?

- Take pramipexole dihydrochloride tablets exactly as your doctor tells you to. Your doctor will tell you how many pramipexole dihydrochloride 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 pramipexole dihydrochloride tablets than your doctor tells you to.
- Pramipexole dihydrochloride tablets can be taken with or without food. Taking pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets for any reason. Do not start taking pramipexole dihydrochloride tablets again before speaking with your doctor. If you have Parkinson's disease and are stopping pramipexole dihydrochloride tablets, you should stop pramipexole dihydrochloride tablets slowly over 7 days.

#### What should I avoid while taking pramipexole dihydrochloride tablets?

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

#### What are the possible side effects of pramipexole dihydrochloride tablets?

**Pramipexole dihydrochloride tablets can cause serious side effects, including**

- **falling asleep during normal daily activities.** See "What is the most important information I should know about pramipexole dihydrochloride tablets?"
- **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 pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets. 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 pramipexole dihydrochloride tablets

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. Pramipexole dihydrochloride tablets are one of the medicines used to treat Parkinson's disease, therefore, patients being treated with pramipexole dihydrochloride tablets should have periodic skin examinations.

There have been reports of patients taking certain medicines to treat Parkinson's disease, including pramipexole dihydrochloride tablets, 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 pramipexole dihydrochloride tablets?

- Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [see USP Controlled Room Temperature].
- Keep pramipexole dihydrochloride tablets out of light.
- **Keep pramipexole dihydrochloride tablets and all medicines out of the reach of children.**

#### General information about pramipexole dihydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not take pramipexole dihydrochloride tablets for a condition for which it was not prescribed. Do not share pramipexole dihydrochloride tablets 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 pramipexole dihydrochloride tablets. For more information, talk with your doctor or pharmacist. They can give you information about pramipexole dihydrochloride tablets that is written for healthcare professionals. **For additional information, you may also call Breckenridge Pharmaceutical, Inc., at 1-800-367-3395.**

#### What are the ingredients in pramipexole dihydrochloride tablets?

**Active Ingredient:** pramipexole dihydrochloride monohydrate

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

Manufactured for: Breckenridge Pharmaceutical, Inc.  
Boca Raton, FL 33487

Manufactured by: Bluepharma® Indústria Farmacêutica, S.A.  
Coimbra, Portugal

Iss: April 2010

PatInfo 628/629/630/631/632/110110