

## Patient Information

# **Pramipexole Dihydrochloride (PRAM-i-PEX-ole dye-HYE-droe-KLOR-ide) Extended-Release Tablets**

Read this Patient Information before you start taking pramipexole dihydrochloride extended-release tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

### **What is pramipexole dihydrochloride extended-release tablet?**

Pramipexole dihydrochloride extended-release tablets are a prescription medicine used to treat the signs and symptoms of Parkinson's disease.

**It is not known if pramipexole dihydrochloride extended-release tablets are safe and effective in children.**

### **What should I tell my doctor before taking pramipexole dihydrochloride extended-release tablets?**

**Before taking pramipexole dihydrochloride extended-release tablets, tell your doctor if you:**

- feel sleepy during the day
- have low blood pressure, or if you feel dizzy or faint, especially when getting up from a sitting or lying down.
- have trouble controlling your muscles (dyskinesia).
- have kidney problems.
- drink alcohol. Alcohol can increase the chance that pramipexole dihydrochloride extended-release tablets will make you feel sleepy or fall asleep when you should be awake.
- are pregnant or plan to become pregnant. It is not known if pramipexole dihydrochloride extended-release tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if pramipexole dihydrochloride will pass into your breast milk. You and your doctor should decide if you will take pramipexole dihydrochloride extended-release tablets or breast-feed. You should not do both.

**Tell your doctor about all the medicines you take, including** prescription and over-the-counter medicines, vitamins, and herbal supplements.

Pramipexole dihydrochloride extended-release tablets and other medicines may affect each other causing side effects. Pramipexole dihydrochloride extended-release tablets may affect the way other medicines work, and other medicines may affect how pramipexole dihydrochloride extended-release tablets works.

### **Especially tell your doctor if you take:**

- medicines called neuroleptics (phenothiazines, butyrophenones, thioxanthenes) or metoclopramide. Pramipexole dihydrochloride extended-release tablets may not work as well if you take these medicines.
- pramipexole dihydrochloride tablets. Pramipexole is the active ingredient in both pramipexole dihydrochloride extended-release tablets and pramipexole dihydrochloride tablets. If you are taking pramipexole dihydrochloride tablets, you should not take pramipexole dihydrochloride extended-release tablets.
- any other medicines that make you sleepy or may increase the effects of pramipexole dihydrochloride extended-release tablets, such as cimetidine (Tagamet).

Ask your doctor for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

### **How should I take pramipexole dihydrochloride extended-release tablets?**

- Pramipexole dihydrochloride extended-release tablet is taken once daily.
- Your doctor will tell you how much pramipexole dihydrochloride extended-release tablets to take and when to take it. Do not take more or less pramipexole dihydrochloride extended-release tablets than your doctor tells you to.
- Swallow pramipexole dihydrochloride extended-release tablets whole. Do not chew, crush, or cut pramipexole dihydrochloride extended-release tablets.
- Pramipexole dihydrochloride extended-release tablets can be taken with or without food. Taking pramipexole dihydrochloride extended-release tablets with food may lower your chances of getting nausea.
- You may see something that looks like a swollen original tablet or swollen pieces of the original tablet in your stool. If this happens, tell your doctor.
- If you miss a dose of pramipexole dihydrochloride extended-release tablet it should be taken as soon as possible, but no later than 12 hours after your regularly scheduled time. If it is later than 12 hours, the missed dose should be skipped and the next dose should be taken on the following day at your regularly scheduled time. **Do not double your next pramipexole dihydrochloride extended-release tablet dose.**

- **Do not stop** taking pramipexole dihydrochloride extended-release tablets without talking to your doctor first. If your doctor tells you to stop taking pramipexole dihydrochloride extended-release tablets, you should ask your doctor for specific instructions on how to slowly and safely discontinue taking pramipexole dihydrochloride extended-release tablets. If you stop taking pramipexole dihydrochloride extended-release tablets you may have withdrawal symptoms (see “withdrawal symptoms” under “What are the possible side effects of pramipexole dihydrochloride extended-release tablets?”)

**What should I avoid while taking pramipexole dihydrochloride extended-release tablets?**

- Do not drink alcohol while taking pramipexole dihydrochloride extended-release tablets. It can increase your chance of having serious side effects. See “What are the possible side effects of pramipexole dihydrochloride extended-release tablets?”
- Do not drive a car, operate a machine, or do other dangerous activities until you know how pramipexole dihydrochloride extended-release tablets affect you. Sleepiness caused by pramipexole dihydrochloride extended-release tablets can happen as late as 1 year after you start your treatment.

**What are the possible side effects of pramipexole dihydrochloride extended-release tablets?**

**Pramipexole dihydrochloride extended-release tablets may cause serious side effects, including:**

- **falling asleep during normal daily activities.** Pramipexole dihydrochloride extended-release tablets may cause you to fall asleep while you are doing daily activities such as driving, talking with other people, or eating.
  - Some people taking the medicine in pramipexole dihydrochloride extended-release tablets have had car accidents because they fell asleep while driving.
  - Some people did not feel sleepy before they fell asleep while driving. You could fall asleep without any warning.

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

- **low blood pressure when you sit or stand up quickly.** After you have been sitting or lying down, stand up slowly until you know how pramipexole dihydrochloride extended-release tablets affect you. This may help reduce the following symptoms while you are taking pramipexole dihydrochloride extended-release tablets

- dizziness
- nausea
- fainting
- sweating

- **unusual urges.** Some people who take certain medicines to treat Parkinson’s disease, including pramipexole dihydrochloride extended-release tablets, have reported problems, such as gambling, compulsive eating, compulsive buying, and increased sex drive.

If you or your family members notice that you are developing unusual urges or behaviors, talk to your doctor.

- **hallucinations and other psychotic-like behavior (seeing visions, hearing sounds or feeling sensations that are not real, confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs and disorganized thinking).** The chances of having hallucinations or and other psychotic-like changes are higher in people taking pramipexole dihydrochloride extended-release tablets for Parkinson's disease who are elderly (age 65 or older).

If you have hallucinations or other psychotic-like changes, talk with your doctor right away.

- **uncontrolled sudden movements (dyskinesia).** If you have new dyskinesia, or your existing dyskinesia gets worse, tell your doctor.
- **posture changes.** Talk with your doctor if you have posture changes you cannot control. These may include your neck bending forward, bending forward at the waist, or tilting sideways when you sit, stand, or walk.
- **withdrawal symptoms.** Pramipexole dihydrochloride extended-release tablet is a dopamine agonist medicine. Dopamine agonist medicines, including pramipexole dihydrochloride extended-release tablets, can cause withdrawal symptoms as your dose is slowly lowered (tapered) or when treatment with pramipexole dihydrochloride extended-release tablets is stopped. Tell your doctor right away if you get any of the following withdrawal symptoms:

- fever
- confusion
- severe muscle stiffness
- feeling like you do not care about things you usually care about (apathy)
- anxiety
- depression
- fatigue
- insomnia
- sweating
- pain

After you have stopped taking pramipexole dihydrochloride extended-release tablets, your doctor may need to restart you at a low dose of pramipexole dihydrochloride extended-release tablets if you get severe withdrawal symptoms.

The most common side effects in people taking pramipexole dihydrochloride extended-release tablets for early Parkinson's disease are:

- nausea and vomiting
- constipation
- dizziness
- fatigue
- dry mouth
- swelling of the feet and ankles

The most common side effects in people taking pramipexole dihydrochloride extended-release tablets who have later stage Parkinson's disease are nausea, constipation, headache and weight loss (anorexia).

These are not all the possible side effects of pramipexole dihydrochloride extended-release tablets. Tell your doctor if you have any side effect that bothers you.

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 pramipexole dihydrochloride extended-release tablets?**

- Store pramipexole dihydrochloride extended-release tablets at room temperature between 15° to 30°C (59° to 86°F).
- Keep pramipexole dihydrochloride extended-release tablets away from high humidity or moisture.
- Keep pramipexole dihydrochloride extended-release tablets and all medicines out of the reach of children.

#### **General Information about the safe and effective use of pramipexole dihydrochloride extended-release tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use pramipexole dihydrochloride extended-release tablets for a condition for which it was not prescribed. Do not give pramipexole dihydrochloride extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about pramipexole dihydrochloride extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for more information about pramipexole dihydrochloride extended-release tablets that is written for healthcare professionals.

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

#### **What are the ingredients in pramipexole dihydrochloride extended-release tablets?**

**Active Ingredient:** Pramipexole dihydrochloride monohydrate USP

**Inactive Ingredients:** betadex, microcrystalline cellulose, ethylcellulose, hydroxypropyl methyl cellulose, colloidal silicon dioxide, and magnesium stearate

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

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Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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