

PATIENT INFORMATION

Pramipexole Dihydrochloride (PRAM-i-PEX-ole Dye-HYE-droe-KLOR-ide) Tablets

Read this Patient Information before you start taking pramipexole dihydrochloride 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 tablet?

Pramipexole dihydrochloride tablet is a prescription medicine used to treat:

- signs and symptoms of Parkinson's disease (PD)
- moderate to severe primary Restless Legs Syndrome (RLS)

It is not known if pramipexole dihydrochloride is safe and effective in children.

What should I tell my doctor before taking pramipexole dihydrochloride?

Before taking pramipexole dihydrochloride, tell your doctor 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 sitting or lying down
- have trouble controlling your muscles (dyskinesia)
- have kidney problems
- drink alcohol. Alcohol can increase the chance that pramipexole dihydrochloride will make you feel sleepy or fall asleep when you should be awake.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if pramipexole dihydrochloride will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if pramipexole dihydrochloride passes into your breast milk. You and your doctor should decide if you will take pramipexole dihydrochloride or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The combination of pramipexole dihydrochloride and other medicines may affect each other and may cause side effects. Pramipexole dihydrochloride may affect the way other medicines work, and other medicines may affect how pramipexole dihydrochloride works.

Especially tell your doctor if you take:

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

- Take pramipexole dihydrochloride tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much pramipexole dihydrochloride tablets to take and when to take it. Do not take more or less pramipexole dihydrochloride tablets than your doctor tells you to.
- Your doctor may change your dose if needed.
- 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 take more pramipexole dihydrochloride tablets than your doctor recommends, call your doctor or go to the nearest hospital emergency room right away.
- If you miss a dose, **do not double your next dose**. Skip the dose you missed and take your next regular dose.
- **Do not** stop taking pramipexole dihydrochloride tablets without talking to your doctor first. If your doctor tells you to stop taking pramipexole dihydrochloride tablets, you should ask your doctor for specific instructions on how to safely discontinue taking pramipexole dihydrochloride tablets. If you stop pramipexole dihydrochloride tablets you may have withdrawal symptoms (see "withdrawal symptoms" under "**What are the possible side effects of pramipexole dihydrochloride tablets?**").

What should I avoid while taking pramipexole dihydrochloride tablets?

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

What are the possible side effects of pramipexole dihydrochloride tablets?

Pramipexole dihydrochloride tablets may cause serious side effects, including:

- **falling asleep during normal daily activities.** Pramipexole dihydrochloride 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 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.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.** You may have:
 - dizziness
 - nausea
 - fainting
 - sweating

Sit and stand up slowly after you have been sitting or lying down.

- **unusual urges.** Some people who take certain medicines to treat Parkinson's disease or RLS, including pramipexole dihydrochloride 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 other psychotic-like changes are higher in people taking pramipexole dihydrochloride 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 tablet is a dopamine agonist medicine. Dopamine agonist medicines, including pramipexole dihydrochloride tablets, can cause withdrawal symptoms as your dose is slowly lowered (tapered) or when treatment with pramipexole dihydrochloride tablet 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 tablets, your doctor may need to restart you at a low dose of pramipexole dihydrochloride tablets if you get severe withdrawal symptoms.

The most common side effects in people taking pramipexole dihydrochloride tablets for Restless Legs Syndrome are nausea and headache.

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

- nausea
- dizziness
- insomnia
- constipation
- muscle weakness
- abnormal dreams
- confusion
- memory problems (amnesia)
- urinating more often than normal

These are not all the possible side effects of pramipexole dihydrochloride 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 tablets?

- Store pramipexole dihydrochloride tablets at room temperature from 68°F to 77°F (20°C to 25°C).
- Keep pramipexole dihydrochloride tablets out of the light.
- Keep pramipexole dihydrochloride tablets and all medicines out of the reach of children.

General Information about the safe and effective use of pramipexole dihydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use pramipexole dihydrochloride tablets for a condition for which it was not prescribed. Do not give pramipexole dihydrochloride 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 tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about pramipexole dihydrochloride tablets that is written for healthcare professionals.

For more information about pramipexole dihydrochloride tablets, call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in pramipexole dihydrochloride tablets?

Active Ingredient: Pramipexole dihydrochloride monohydrate USP

Inactive Ingredients: betacyclodextrin (betadex), colloidal silicon dioxide, corn starch, magnesium stearate, microcrystalline cellulose and povidone.

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

All trademarks are property of their respective owners.

Manufactured by:

Alembic Pharmaceuticals Limited

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA