PATIENT MEDICATION INFORMATION

[Pr]PRAMIPEXOLE
(pramipexole dihydrochloride tablets)

Read this carefully before you start taking Pramipexole and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Pramipexole.

Serious Warnings and Precautions

You may feel sleepy, drowsy, or, rarely, may suddenly fall asleep without warning (i.e., without feeling sleepy or drowsy) when taking Pramipexole. When you are taking Pramipexole, you should not drive, operate machinery, or take part in activities that require you to be alert. You may put yourself and others at risk for serious injury or death. Falling asleep suddenly without warning has also been reported in patients taking similar medicines to treat Parkinson's disease.

Talk to your healthcare professional **right away** if you:

- feel drowsy or
- suddenly fall asleep

What is Pramipexole used for?

Pramipexole is used in adults to treat:

- the signs and symptoms of Parkinson's disease. It may be used alone or with another medicine called levodopa.
- the symptoms of moderate to severe Restless Legs Syndrome.

How does Pramipexole work?

Pramipexole belongs to a group of medicines known as dopamine agonists. It is thought to work by stimulating dopamine receptors in the brain. Dopamine is a naturally occurring chemical produced by certain brain cells. It has the role of relaying messages in certain regions of the brain that control muscle movement. Difficulty in movement results when too little dopamine is produced. In many patients, this reduces the symptoms of Parkinson's disease and Restless Legs Syndrome.

What are the ingredients in Pramipexole?

Medicinal ingredient: Pramipexole dihydrochloride monohydrate.

Non-medicinal ingredients: Betacyclodextrin-Kleptose, microcrystalline cellulose, magnesium stearate, povidone, corn starch and colloidal silicon dioxide.

Pramipexole comes in the following dosage forms:
Tablet: 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg.

Do not use Pramipexole if:

- you are allergic to pramipexole, or any of the non-medicinal ingredients in Pramipexole.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Pramipexole. Talk about any health conditions or problems you may have, including if you:

- have blood pressure problems;
- have kidney problems;
- have heart or blood vessel problems (cardiovascular disease);
- have albinism (reduced amount of melanin or no melanin at all) or ocular albinism (reduced color in the colored part of the eye and the retina);
- are pregnant, think you might be pregnant or are planning to become pregnant. Your healthcare professional will advise you whether you should take Pramipexole while you are pregnant;
- are breast-feeding or plan to breast-feed;
- have any mental health problems;
- are taking levodopa, a medication used to treat the symptoms of Parkinson's disease;
- suffer from muscle twitching or unusual/abnormal movement of the face, arms, legs or other parts of your body (dyskinesia);
- are taking medication to treat mental health problems;
- are 65 years of age or older

Other warnings you should know about:

Blood pressure: Pramipexole may cause low blood pressure at any time or when you go from sitting or lying down to standing. This may be more likely to happen when your dose is increased. Your healthcare professional should monitor you for signs and symptoms of low blood pressure.

Augmentation of Restless Legs Syndrome symptoms: If you are taking Pramipexole for Restless Legs Syndrome (RLS), Pramipexole may cause augmentation. Augmentation is when you experience symptoms earlier in the evening (or even in the afternoon), increased intensity of symptoms, and spread of symptoms to other parts of your body. Sometimes augmentation may happen when your dose of Pramipexole is increased. Your healthcare professional will monitor you to see if your symptoms become worse. They may change your dose or stop your treatment with Pramipexole. Stopping Pramipexole can also cause rebound RLS. This means your RLS

symptoms can come back in the early morning and be worse than before you started taking pramipexole.

Reducing your dose of Pramipexole or stopping your treatment: Do NOT suddenly stop taking Pramipexole or lower your dose without talking to your healthcare professional first. If you do this, it may cause you to have:

- symptoms resembling Neuroleptic Malignant Syndrome. This is a disorder that causes you to have a fever, muscle stiffness, confusion, altered mental status, unstable blood pressure, and increased heartbeat
- Dopamine Agonist Withdrawal Syndrome (DAWS), a drug withdrawal syndrome. This includes withdrawal symptoms such as apathy, anxiety, depression, fatigue, sweating, panic attacks, insomnia, irritability, and pain

Stopping your treatment must be a gradual process that you discuss with your healthcare professional. Your healthcare professional should monitor you when your dose is reduced or when you stop taking Pramipexole.

Impulse control disorders: During treatment with Pramipexole, impulse control disorders have been observed, which signs and symptoms may include:

- developing urges or cravings to behave in ways that are unusual for you; or
- you are unable to resist the impulse, drive, or temptation to carry out certain activities that could harm yourself or others.

Tell your healthcare professional right away if you, your family, or caregiver notices that you are showing signs of impulse control disorders. This can include:

- addictive gambling;
- excessive buying or spending;
- binge eating or compulsive eating; and
- abnormally high sex drive or an increase in sexual activity.

Your healthcare professional may change your dose if you develop an impulse control disorder or signs of one.

Dopamine Dysregulation Syndrome: You may feel a craving to take more Pramipexole than you are supposed to take. This is called Dopamine Dysregulation Syndrome and can lead to you taking too much Pramipexole. If you feel the desire to take more Pramipexole than you are supposed to take, talk to your healthcare professional.

Mental health problems and hallucinations: Pramipexole may cause:

- hallucinations (seeing or hearing things that are not there) and confusion. This may be more likely to happen if you are 65 years of age or older.
- thoughts, feelings, or actions of suicide
- psychotic-like behaviour such as delusions, paranoia, and trouble thinking clearly and logically.

Tell your healthcare professional right away if you start to develop unusual behaviour, feel depressed or have thoughts of suicide.

Skin cancer: People with Parkinson's disease have a higher risk of developing skin cancer (melanoma). Your healthcare professional should monitor you for skin cancer while you are taking Pramipexole. Tell your healthcare professional if you have:

- suspicious, undiagnosed changed patches of pigmented skin
- irritated or irregular moles
- moles in which you have noticed changes

Dystonia: A movement disorder called dystonia may happen when you first start taking Pramipexole, several months after starting Pramipexole or when your dose of Pramipexole is changed. Tell your healthcare professional if you are unable to keep your body and neck straight and upright or have twisting movements that you cannot control. If this happens your healthcare professional may change your dose of Pramipexole.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Pramipexole:

- Levodopa/carbidopa (used to treat Parkinson's disease).
- Amantadine (used to treat Parkinson's disease and used to treat viral infections);
- Medications used to treat ulcers (such as cimetidine and ranitidine);
- Medications used to treat high blood pressure and chest pain (such as diltiazem and verapamil);
- Triamterene (used to treat fluid retention in people with heart failure);
- Quinidine (used to treat heart rhythm conditions);
- Quinine (used to treat malaria);
- Antipsychotic medications (such as phenothiazines, butyrophenones, thioxanthines and metoclopramide).
- Avoid alcohol or other sedatives while taking Pramipexole.

How to take Pramipexole:

- Take Pramipexole exactly as your healthcare professional has told you. Talk to your healthcare professional if you are not sure.
- Do NOT stop taking Pramipexole, reduce the amount of Pramipexole you take or change your dose unless your healthcare professional tells you to.
- Swallow Pramipexole with water. It can be taken with or without food.

Usual dose:

Note: Pramipexole is NOT available in 0.125 mg strength.

Parkinson's disease

Usual starting dose: Your healthcare professional will determine the starting dose that is right for you. The usual starting dose is 0.125 mg three times a day. If you have kidney problems, your healthcare professional may start you at a lower dose.

Depending on your response and tolerance, your healthcare professional will increase your dose to find the right dose for you.

Maximum daily dose: 4.5 mg a day.

Restless Legs Syndrome

Usual starting dose: 0.125 mg once a day taken 2-3 hours before bedtime. Depending on your response and tolerance, your healthcare professional will increase your dose to find the right dose for you.

Maximum daily dose: 0.5 mg a day.

Overdose:

Signs of an overdose may include:

- nausea
- vomiting
- excessive movement
- hallucinations
- feeling agitated
- low blood pressure

If you think you, or a person you caring for, have taken too much Pramipexole, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you have missed a dose, skip the missed dose and take the next dose at the usual time. Do not take a double dose to make up for the one you missed.

What are the possible side effects from using Pramipexole?
These are not all the possible side effects you may have when taking Pramipexole. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- nausea
- constipation
- sleepiness
- dizziness
- unusual dreams
- memory loss
- fatigue
- muscle weakness
- restlessness
- changes in weight
- increased or decreased appetite
- hiccups
- increase in cholesterol
- lung infection (pneumonia)
- headache
- unusually overactive movement (hyperkinesia)
- fainting
- vision problems such as seeing double, blurred vision, reduced vision
- shortness of breath
- vomiting
- swelling of hands, ankles or feet
- diarrhea
- accidental injury
- spontaneous erection of the penis

Serious side effects and what to do about them			
Symptom / effect	**Talk to you healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Augmentation of Restless Legs Syndrome (RLS): symptoms of RLS happen earlier in the evening (or even in the afternoon), increased intensity of symptoms, and spread of symptoms to other parts of the body.		✓	
Dyskinesia (difficulty		✓	

performing voluntary movements): muscle twitching or unusual/abnormal movement of the face or tongue or other parts of your body			
COMMON			
Hallucinations (seeing or hearing things that are not there) and confusion		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Insomnia (Difficulty falling asleep)		✓	
RARE			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, itchy swellings on the skin, hives or rash, intense itching, swelling of the face, lips, tongue or throat			✓
Excessive sleepiness or falling asleep without warning while doing normal activities		✓	
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue, and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓
Impulse control disorder (urges and behaviours that		✓	

are unusual): addictive gambling, addiction to other medicines, excessive buying or spending, binge eating or compulsive eating, or abnormally high sex drive or an increase in sexual activity			
Mental health problems: false beliefs (delusion), paranoia, extreme changes in mood or emotions (mania), anxiety, delirium, depression, irritability, reduced sex drive, altered mood, nervousness, restlessness, thoughts of death or suicide		✓	
UNKNOWN FREQUENCY			
Dopamine Agonist Withdrawal Syndrome (DAWS): depression, apathy, anxiety, fatigue, sweating, panic attacks, insomnia, irritability or pain may occur after stopping or reducing dose		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

- Store at room temperature (15°C to 30°C) and protect from light.
- The expiry date of this medicine is printed on the original container. Do not use the medicine after this date.
- Keep out of reach and sight of children.

If you want more information about Pramipexole:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca
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