PART III: CONSUMER INFORMATION

Pr PRAMIPEXOLE
(pramipexole dihydrochloride tablets)

This leaflet is part III of a three-part "Product Monograph" published when PRAMIPEXOLE was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about PRAMIPEXOLE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRAMIPEXOLE is used to treat early and late stage Parkinson's disease. PRAMIPEXOLE provides relief of signs and symptoms of Parkinson's disease. Signs and symptoms of the disease include: shaking (tremor), slowness in performing activities of daily living (bradykinesia), muscle stiffness (rigidity) and mood changes (depression). In late stage Parkinson's disease, PRAMIPEXOLE will be used in combination with levodopa.

PRAMIPEXOLE is used to treat the symptoms of moderate to severe Restless Legs Syndrome (RLS) which occurs for unknown reasons. Signs and symptoms of RLS include: an urge to move the legs, usually accompanied or caused by uncomfortable and unpleasant leg sensations; symptoms begin or worsen during periods of rest or inactivity; symptoms are partially or totally relieved by movement (walking or stretching) at least as long as the activity continues; symptoms are worse or occur only in the evening or night. You may also experience difficulty falling asleep or occasional jerky legs and/or arms during sleep.

What it does:
PRAMIPEXOLE belongs to a group of medicines known as "dopamine agonists". PRAMIPEXOLE improves some of the chemical imbalance in the part of the brain affected by Parkinson's disease or possibly, Restless Legs Syndrome.

When it should not be used:
If you are allergic to PRAMIPEXOLE, or any of the nonmedicinal ingredients of the product (see list below).

PRAMIPEXOLE is not recommended for children under 18 years of age.

What the medicinal ingredient is:
Pramipexole dihydrochloride monohydrate.

What the nonmedicinal ingredients are:
Betacyclodextrin-Kleptose, microcrystalline cellulose, magnesium stearate, povidone, corn starch and colloidal silicon dioxide.

What dosage forms it comes in:
PRAMIPEXOLE (pramipexole dihydrochloride monohydrate) tablets are available in strengths of 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg.

WARNINGS AND PRECAUTIONS

You are warned of a sudden onset of sleep condition and the strong desire to sleep which may occur without warning, while taking PRAMIPEXOLE. You should not drive, operate machinery or engage in activities that require alertness, as you may put yourself and others at risk of serious injury or death. This sudden onset of sleep condition has also been reported in patients taking other anti-parkinson's drugs of the same class.

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 drugs used to treat Parkinson's disease. PRAMIPEXOLE is one of the drugs used to treat Parkinson's disease; therefore, patients treated with PRAMIPEXOLE should have periodic skin examinations.

Patients and caregivers should be made aware of the fact that:

- abnormal behaviour such as pathological gambling, increased sexual desire, excessive sexual activity, compulsive shopping or binge eating have been reported. Those changes have also been reported in patients taking other anti-Parkinson's drugs of the same class.
- there is a risk in patients with Parkinson's disease and Restless Legs Syndrome of thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide action (suicide attempt, completed suicide). This risk may still be there even if patients see an improvement in their condition.
- you should not reduce your prescribed dose or stop PRAMIPEXOLE without checking with your physician, as you may experience a set of withdrawal symptoms (called dopamine agonist withdrawal syndrome). Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating, panic attacks, insomnia, irritability or pain after stopping or reducing PRAMIPEXOLE dose. If the problem persists more than a few weeks, your doctor may need to adjust your dose.
- you should not stop suddenly or reduce the doses of anti-Parkinson medications, including PRAMIPEXOLE, without checking with your physician. If you suddenly stop PRAMIPEXOLE you may experience symptoms similar to a neurological disorder (Neuroleptic Malignant Syndrome). The symptoms may be serious and include fever, muscle stiffness, confusion, unstable blood pressure, increased heart beat and depressed level of consciousness (e.g. coma).

BEFORE you use PRAMIPEXOLE talk to your doctor or pharmacist if you:

- have any health problems, especially kidney problems or blood pressure problems;
- have any unusual conditions related to your eyes or eyesight;
- have previously taken PRAMIPEXOLE and became unwell;
- have any allergies or reactions to foods or drugs;
- are pregnant or intend to become pregnant;
- are breast feeding;
- are taking any other medications, including any drugs you can buy without a prescription;
- have any psychotic disorders;
- drive a vehicle or perform hazardous tasks during your work.

INTERACTIONS WITH THIS MEDICATION

Other medications may be affected by PRAMIPEXOLE or may affect how PRAMIPEXOLE works. Do not take any other medication, including over-the-counter medications or herbal products unless your doctor tells you to. Tell any other doctor, dentist or pharmacist who you talk to that you are taking PRAMIPEXOLE.

Drugs that may interact with PRAMIPEXOLE include:

- Levodopa/carbidopa (used to treat Parkinson's disease). PRAMIPEXOLE may increase the frequency of hallucinations;
- Amantadine (used to treat Parkinson's disease and used to treat viral infections);
- Drugs used to treat ulcers (such as cimetidine and ranitidine);
- Drugs 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 (dopamine antagonists such as phenothiazines, butyrophenones, thioxanthines and metoclopramide). PRAMIPEXOLE can make your psychotic symptoms worse;
- Avoid alcohol or other sedatives while taking PRAMIPEXOLE.

PROPER USE OF THIS MEDICATION

Usual Adult dose:

Parkinson's disease

Take PRAMIPEXOLE in equal doses, three times daily as prescribed by your doctor. Dosages should be increased gradually from a starting dose of 0.125 mg three times daily and should not be increased more frequently than every 5 to 7 days. It is important that your doctor increases your dosage of PRAMIPEXOLE gradually to avoid side effects and to achieve the best therapeutic effect. Your dose will probably change each week until your doctor and you decide what the best dose is for you. Make sure that you only use the tablet strength that your doctor has prescribed. The maximal recommended dose of PRAMIPEXOLE is 4.5 mg per day. Lower doses are recommended for patients with kidney disease.

Your doctor may decide to lower your dose of levodopa to prevent excessive side effects and to make sure that you are getting the best results from both drugs. Pay close attention to your doctor's instructions and never change the dose of either drug yourself.

You should not change the dose or discontinue treatment with PRAMIPEXOLE without the recommendation of your doctor.

You may take PRAMIPEXOLE without food or with food if you find that you feel sick to your stomach while taking the tablets.

Restless Legs Syndrome

The recommended starting dose of PRAMIPEXOLE is 0.125 mg taken once daily (2-3 hours before bedtime) as prescribed by your doctor. If it is required, your doctor may change the dose every 4-7 days to achieve the best therapeutic effect. Tablets should be swallowed with water, and can be taken either with or without food. The maximal recommended dose of PRAMIPEXOLE is 0.50 mg per day.

Do not stop taking PRAMIPEXOLE suddenly, as this may result in worsened RLS symptoms. Talk to your doctor about slowly stopping the medication if necessary.

Overdose:

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

If you accidentally take too many tablets, you should get medical help immediately; either by calling your doctor, the regional Poison Control Centre or by going to the nearest hospital (do not drive yourself). Always take the labelled medicine container with you whether or not there are any PRAMIPEXOLE tablets left.

Missed dose:

If you forget to take a dose, take it as soon as you remember, then carry on as before. However, if it is almost time for your next dose, skip the dose you missed and take the next dose when you are supposed to. Do not take more than one dose at a time.

PRAMIPEXOLE has been prescribed for you. Do not give these tablets to anyone else, even if you think they have the same condition as you.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You should be aware that prescription medicines carry some risks and that all possible risks may not be known at this stage. Discuss with your doctor the risks of taking PRAMIPEXOLE against the expected benefits.

If you do experience any unusual or unwanted effects while you are taking PRAMIPEXOLE, be sure to tell your doctor. It is important that he/she knows of any unwanted effects to determine the best dose of PRAMIPEXOLE for you.

- PRAMIPEXOLE may cause unwanted effects such as nausea, constipation, sleepiness, dizziness, dream abnormalities, amnesia (memory loss), fatigue, muscle weakness, restlessness, weight decrease, including decreased appetite, weight increased, hiccups, accidental injury, confusion, increase in cholesterol, aggressive behaviour, pneumonia, abnormal behaviour (reflecting symptoms of impulse control disorders and compulsions), overeating, headache, hyperkinesia (unusually overactive), dystonia (inability of keeping your body and neck straight and upright (axial dystonia)), in particular flexion of the head and neck (also called antecollis), forward bending of the lower back (also called camptocormia) or sidewards bending of the back (also called pleurothotonus or Pisa Syndrome), fainting, visual impairment, including double vision, vision blurred and visual acuity reduced, shortness of breath, vomiting, heart failure, and peripheral oedema (swelling of hands, ankles or feet).
- PRAMIPEXOLE does not usually affect people's normal activities. However, some people may feel dizzy or sleepy while taking PRAMIPEXOLE, especially during the first few weeks of treatment.
- If you are taking PRAMIPEXOLE for RLS you may notice an increase in your symptoms in the early morning or the afternoon/early evening hours. If this happens, please let your doctor know.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Dyskinesia (difficulty performing voluntary movements).		✓	
	Hallucinations (see, hear, smell, taste or feel something that is not there).		✓	
	Insomnia (difficulty falling asleep).		✓	
	Low blood pressure with dizziness when rising to a sitting or standing position. You may feel sick, lightheaded, faint or you may sweat.		✓	
Uncommon	Behavioural changes such as compulsive gambling, compulsive shopping, changes in sexual desire or sexual activity, increased eating.		✓	
	Delusion (a false belief, despite incontrovertible evidence, that something is false).		✓	
	Paranoia (unrealistic and excessive anxiety and worry).		✓	
	Sudden onset of sleep and the strong desire to sleep.		✓	
	Hypersensitivity (allergic reaction) with symptoms such as: red, itchy swellings on the skin, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, rash or intense itching.			✓
Not known	Dopamine Agonist Withdrawal Syndrome (DAWS): depression, apathy, anxiety, fatigue, sweating, panic attacks, insomnia, irritability or pain may occur after stopping or reducing dose.		✓	

Do not be alarmed by this list of possible side effects. You may not experience any of them. This is not a complete list of side effects. For any unexpected effects while taking PRAMIPEXOLE, contact your doctor or pharmacist immediately, so that these effects may be properly addressed.

HOW TO STORE IT

- Keep this drug away from light. PRAMIPEXOLE may change colour when exposed to light.
- PRAMIPEXOLE should be stored between 15°C and 30°C.
- The expiry date of this medicine is printed on the label. Do not use the medicine after this date.
- Keep this drug out of reach and sight of children.

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/adverse-reaction-reporting.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.

MORE INFORMATION

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 Consumer 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 info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée
Laval, Québec
H7L 3W9

Last revised: May 28, 2021.