

**PART III: CONSUMER INFORMATION**Pr **Mirapex**<sup>®</sup>

(Pramipexole Dihydrochloride Tablets)

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

**ABOUT THIS MEDICATION****What the medication is used for:**

MIRAPEX is used to treat early and late stage Parkinson's disease. MIRAPEX 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, MIRAPEX will be used in combination with levodopa.

MIRAPEX 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:**

MIRAPEX belongs to a group of medicines known as "dopamine agonists". MIRAPEX 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 MIRAPEX, or any of the non-medicinal ingredients of the product (see list below).

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

**What the medicinal ingredient is:**

pramipexole dihydrochloride monohydrate

**What the non-medicinal ingredients are:**

Colloidal silicon dioxide, corn starch, magnesium stearate, mannitol and povidone.

**What dosage forms it comes in:**

MIRAPEX (pramipexole dihydrochloride monohydrate) is supplied in bottles of 90 tablets for the 0.25 mg, 0.5 mg, 1.0 mg, and 1.5 mg tablets; the 0.125 mg tablets are available in blister packs of 30 tablets.

**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 MIRAPEX. 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. MIRAPEX is one of the drugs used to treat Parkinson's disease; therefore, patients treated with MIRAPEX 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.

BEFORE you use MIRAPEX 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 MIRAPEX 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 MIRAPEX or may affect how MIRAPEX 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 that you talk to that you are taking MIRAPEX.

Drugs that may interact with MIRAPEX include:

- Levodopa/carbidopa (used to treat Parkinson's disease). MIRAPEX 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);
- Triameterene (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, thioxathines and metoclopramide). MIRAPEX can make your psychotic symptoms worse;
- Avoid alcohol or other sedatives while taking MIRAPEX.

## PROPER USE OF THIS MEDICATION

### Usual Adult dose:

#### **Parkinson's disease**

Take MIRAPEX 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 MIRAPEX 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 MIRAPEX 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 MIRAPEX without the recommendation of your doctor.

You may take MIRAPEX 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 MIRAPEX 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 MIRAPEX is 0.50 mg per day.

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

### Overdose:

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 MIRAPEX 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.

MIRAPEX 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 MIRAPEX against the expected benefits.

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

- MIRAPEX 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 sideways 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).
- MIRAPEX does not usually affect people’s normal activities. However, some people may feel dizzy or sleepy while taking MIRAPEX, especially during

the first few weeks of treatment.

- If you are taking MIRAPEX 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.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		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, light-headed, 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)		✓	

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Sudden onset of sleep and the strong desire to sleep		✓	
<b>Uncommon</b> 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			✓

*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 MIRAPEX, contact your doctor or pharmacist immediately, so that these effects may be properly addressed.*

**HOW TO STORE IT**

- Keep this drug away from light. MIRAPEX may change colour when exposed to light.
- MIRAPEX should be stored at room temperature

(15 - 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 the reach 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.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**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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