PART III: CONSUMER INFORMATION

[Pr]PRAMIPEXOLE
Pramipexole Dihydrochloride Monohydrate 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. Sign 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.

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.

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 important nonmedicinal ingredients are:
Magnesium stearate, microcrystalline cellulose and starch (corn).

What dosage forms it comes in:
Tablets, 0.25 mg, 0.5 mg, 1.0 mg, 1.5 mg

WARNINGS AND PRECAUTIONS

You are warned of a sudden onset of sleep condition which may occur without warning, while taking PRAMIPEXOLE. You should not 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 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 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 drugs of the same class.

BEFORE you use PRAMIPEXOLE talk to your doctor or pharmacist:

- if you have any health problems, especially kidney problems or blood pressure problems;
- if you have any unusual conditions related to your eyes or eyesight;
- if you have previously taken PRAMIPEXOLE and became unwell;
- if you have any allergies or reactions to foods or drugs;
- if you are pregnant or intend to become pregnant;
- if you are breast feeding;
- if you are taking any other medications, including any drugs you can buy without a prescription.
- If you 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 that you talk to that you are taking PRAMIPEXOLE.

Avoid alcohol or other sedatives while taking PRAMIPEXOLE.

PROPER USE OF THIS MEDICATION

Usual 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.

Overdose:

If you accidentally take too many tablets, you should get medical help immediately; either by calling your doctor or by going to the nearest hospital (do not drive yourself), or by contacting the nearest regional poison centre.

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.

- PRAMIPEXOLE may cause unwanted effects such as nausea, constipation, sleepiness, dream abnormalities, amnesia, fatigue, muscle weakness, restlessness, weight decrease, visual disturbance, accidental injury and confusion. 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 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.

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	
Common	Dyskinesia (Difficulty performing voluntary movements)		√	
	Hallucinations (see, hear, smell, taste or feel some-thing 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	Behavioral changes such as compulsive gambling, compulsive shopping, changes in sexual desire or sexual activity, increased eating		√	

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	
	Delusion (a false belief, despite incontrovertible evidence, that something is false)		√	
	Paranoia (unrealistic and excessive anxiety and worry)		√	
	Sudden onset of sleep		√	

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

- PRAMIPEXOLE should be stored at room temperature 15 - 30°C (59-86°F).
- 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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health product to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free to 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701C
    Ottawa, ON K1A 0K9

    Postage paid labels, Canada Vigilance Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you should require information related to the management of side effects, contact your health professional. 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 by contacting Sanis Health Inc. at:

1-866-236-4076
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