

PART III: CONSUMER INFORMATION

Pr ROPINIROLE

Ropinirole Tablets, USP

0.25 mg, 1 mg ropinirole
(as ropinirole hydrochloride)

This leaflet is part III of a three-part "Product Monograph" published when ROPINIROLE was approved for sale in Canada and is designed specifically for Consumers.

Please read this information before you start to take your medicine. Keep this leaflet until you have finished all your tablets as you may need to read it again. If you are helping someone else to take ROPINIROLE, read this leaflet before you give the first tablet.

This leaflet is a summary and will not tell you everything about ROPINIROLE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ROPINIROLE, also known as ropinirole is used to treat the signs and symptoms of Parkinson's disease.

You may receive ROPINIROLE on its own, but it may also be given with another drug used to treat Parkinson's disease.

What it does:

ROPINIROLE belongs to the family of medicines called dopamine agonists. ROPINIROLE improves some of the chemical imbalance in the part of the brain affected by Parkinson's disease.

When it should not be used:

Do not use ROPINIROLE if you are allergic to it or any of the components of its formulation (see list below). ROPINIROLE is not recommended for children under 18 years of age.

What the medicinal ingredient is:

Ropinirole hydrochloride

What the nonmedicinal ingredients are:

Non-medicinal ingredients include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, FD&C Blue #2 (1mg), iron oxide yellow (1mg).

What dosage forms it comes in:

ROPINIROLE is available as 0.25 mg (white) and 1 mg (green) tablets.

WARNINGS AND PRECAUTIONS

You are warned of a sudden onset of sleep condition which may occur without warning, while taking ROPINIROLE. 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 similar anti-Parkinson drugs.

What should I know before taking ROPINIROLE:

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

Drop in Blood Pressure

While taking ROPINIROLE you may experience a drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position.

Neurological Disorder

Symptoms resembling a neurological disorder (Neuroleptic Malignant Syndrome) characterized by fever, muscle stiffness, stupor and unstable involuntary actions have been reported in relation to changes in treatment, reduction of treatment dose and stopping treatment,

ROPINIROLE taken with L-dopa

ROPINIROLE may amplify the side effects of L-dopa (also called levodopa) and may cause or worsen pre-existing uncontrolled jerky movements (dyskinesia). Tell your doctor if this happens as the dose of your medicines may need adjusting.

Eye Disorders

If you have albinism (lack of pigment in skin or hair), you may have an increased risk of eye disorders while taking ROPINIROLE compared to people without albinism. Therefore, you should take ROPINIROLE only under an ophthalmologist's (doctor who specializes in eye disorders) care.

Hallucinations

While taking ROPINIROLE, you may experience hallucinations, such as seeing or hearing things that aren't really there.

Psychiatric Disorders

Impulse control symptoms including compulsive behaviours, e.g. feeling an urge to gamble, hypersexuality, compulsive shopping, or binge eating, as well as aggression have been reported with the use of ROPINIROLE.

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

- **have any health problem, especially any heart, liver or kidney condition.**
- **have previously taken ropinirole and became unwell.**
- **have any allergies or reactions to foods or drugs.**
- **are pregnant or think you may be pregnant, or if you are breast feeding. You should not be taking ROPINIROLE if you are pregnant or breast feeding.**
- **are taking any other medications, including any drugs you can buy without a prescription.**
- **have experienced any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour). (See SIDE EFFECTS AND WHAT TO DO ABOUT THEM)**

INTERACTIONS WITH THIS MEDICATION

Other medications may be affected by ROPINIROLE or may affect how ROPINIROLE works. Do not take any other medication, including any drugs or herbal products you can buy without a prescription. Tell any other doctor, dentist or pharmacist that you talk to that you are taking ROPINIROLE.

Drug-drug Interaction:

Drugs that may interact with ROPINIROLE include:

- a drug used to help with breathing difficulties called theophylline
- an antibiotic called ciprofloxacin
- any hormone replacement therapy (HRT)
- other dopamine agonists, e.g. L-dopa: ROPINIROLE may make some of the side effects of L-dopa worse, e.g. jerky movement.
- certain medicines called neuroleptics used to treat schizophrenia and other serious mental illnesses
- digoxin, a heart medicine that is used to treat congestive heart failure or certain heartbeat irregularities

Drug-lifestyle Interaction:

- ROPINIROLE may affect your ability to remain alert while doing normal daily activities. You should refrain yourself from doing activities such as driving a car doing physical tasks or using hazardous machinery until you know how ROPINIROLE affects you.
- Because ROPINIROLE can make you feel sleepy, tell your doctor or pharmacist if you are planning to drink alcohol.

Before making any change to other medications you are taking, or stopping them, talk to your doctor first.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow the doctor's instructions about how and when you should take your tablets. Your doctor will decide how many tablets you

need to take each day and you should always follow his/her instructions. When you first start taking ROPINIROLE, the amount you take will be increased gradually.

Your doctor may adjust the amount that you are taking. You will usually be told to take ROPINIROLE three times a day. You should not change the dose or discontinue treatment with ROPINIROLE without the recommendation of your doctor.

If you are taking other medicines for Parkinson's disease, the doctor may adjust the dose of these medicines while you are taking ROPINIROLE.

You should swallow the tablets whole with water. Do not chew. ROPINIROLE can be taken with or without food.

You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for the medicine to work.

REMEMBER: THIS MEDICINE IS FOR THE PERSON NAMED BY THE DOCTOR. DO NOT GIVE IT TO ANYBODY ELSE.

Overdose:

If you think you have taken too much ROPINIROLE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you or someone you know have taken too many tablets all at once, you should get medical help immediately, either by calling your doctor, the Regional Poison Control Centre, or the nearest hospital (do not drive yourself). Always take the labelled medicine container with you even if there are no tablets left.

Missed Dose:

If you have forgotten to take ROPINIROLE, do not take extra doses to make up for the forgotten individual doses. When you do remember to take ROPINIROLE, take your next dose of ROPINIROLE at the usual time. If you have missed taking ROPINIROLE for one day or more consult your doctor for advice on restarting ROPINIROLE.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, ROPINIROLE tablets can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor if you experience these or other side effects.

Some of the most commonly reported side effects of ropinirole tablets are:

- Feeling or being sick
- Stomach ache

- Dizziness or light-headedness, fainting
- Sleepiness
- Headache
- Some leg swelling
- Tiredness
- Viral infection
- Feeling full and bloated or experiencing heartburn

Keep your tablets in their original pack in a dry place away from light and moisture. They should be kept at room temperature (between 15 to 30°C). Close container tightly after each use.

Keep out of reach of children.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency assistance
		Only if severe	In all cases	
Very Common	Uncontrollable movements (dyskinesias)		✓	
Common	Hallucinations, feeling confused		✓	
Uncommon	Having severe confusion, irrational ideas or feeling irrational suspiciousness, other psychotic reactions, impulse control (symptoms like increased libido, feeling the urge to gamble, to shop or eat, acting in an aggressive manner)		✓	
Very rare	Allergic reactions (symptoms like red, itchy swellings on the skin, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, rash or intense itching)			✓
	Extreme sleepiness, falling asleep without warning		✓	

This is not a complete list of side effects. For any unexpected effects while taking ROPINIROLE, contact your doctor or pharmacist.

HOW TO STORE IT

The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 by contacting the sponsor, Sanis Health Inc., at:
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