

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

**Pr PRO-LEVOCARB
Levodopa and Carbidopa Tablets**

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

Remember – This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

ABOUT THIS MEDICATION

PRO-LEVOCARB is available **only on prescription** from your physician.

What the medication is used for:

Your physician has prescribed PRO-LEVOCARB to treat the symptoms of Parkinson's disease. Parkinson's disease is a chronic disorder characterized by slow and unsteady movement, muscular stiffness, and tremor. If untreated, Parkinson's disease can cause difficulty in performing normal daily activities.

What it does:

PRO-LEVOCARB is a combination of levodopa, the metabolic precursor of dopamine, and carbidopa, an aromatic amino acid decarboxylase inhibitor. It treats the symptoms of Parkinson's disease.

It is believed that the symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine 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.

Levodopa acts to replenish dopamine in the brain, while carbidopa ensures that enough levodopa gets to the brain where it is needed. In many patients, this reduces the symptoms of Parkinson's disease.

When it should not be used:

Do not take PRO-LEVOCARB:

- are allergic to any of its ingredients
- have any suspicious skin lesions (moles)

which have not been examined by your doctor or if you have ever had skin cancer

- are being treated with certain MAO inhibitor drugs, such as for depression, within the last 2 weeks
- have narrow-angle glaucoma
- have untreated heart, liver, kidney, lung, blood or hormonal disease
- have been told that you should not take sympathomimetic drugs such as isoproterenol, amphetamines, epinephrine or cough and cold medications containing drugs related to epinephrine.

What the medicinal ingredient is:

Levodopa and Carbidopa

What the important nonmedicinal ingredients are:

croscarmellose sodium, magnesium stearate, microcrystalline cellulose and sorbitol. The 100 mg/10 mg and 250 mg/25 mg tablets also contain Indigotine AL Lake 13% (Blue #2) and Brilliant Blue FCF Lake 12%. The 100 mg/25 mg tablets contain D&C Yellow #10 Lake 15 - 16%.

What dosage forms it comes in:

PRO-LEVOCARB tablets are available in a levodopa:carbidopa 4:1 ratio (PRO-LEVOCARB 100 mg/25 mg) and in a 10:1 ratio of levodopa to carbidopa (PRO-LEVOCARB 100 mg/10 mg and 250 mg/25 mg).

WARNINGS AND PRECAUTIONS

Some people feel sleepy, drowsy, or, rarely, may suddenly fall asleep without warning (i.e. without feeling sleepy or drowsy) when taking PRO-LEVOCARB. During treatment with PRO-LEVOCARB take special care when you drive or operate a machine. If you experience excessive drowsiness or a sudden sleep onset episode, refrain from driving and operating machines, and contact your physician

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. Therefore, patients treated with PRO-LEVOCARB should have periodic skin examinations.

Before starting Pr PRO-LEVOCARB tell your doctor or pharmacist if:

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- have or have had any medical conditions including: allergies; depression or mental disturbances; lung, kidney, liver, heart or hormonal problems; skin cancer or suspicious skin lesions; ulcer in your gut (called “duodenal” or “peptic ulcer”); convulsions/seizures; or glaucoma
- have previously been treated with levodopa
- are pregnant or plan to become pregnant
- are breastfeeding or wish to breastfeed
- are going to have an operation that requires general anesthesia
- drive or operate machinery

Tell your doctor if you or your family member/caregiver notices you are developing urges to gamble, increased sexual urges, excessive eating or spending, and/or other intense urges that could harm yourself or others. These behaviors are called impulse control disorders. Your doctor may need to review your treatments.

It is not recommended to use PRO-LEVOCARB while you are pregnant or breast-feeding. It is not known what effect PRO-LEVOCARB may have on human pregnancy. Levodopa, one of the components of PRO-LEVOCARB, is passed into human milk. If you are pregnant, may become pregnant or intend to breast-feed, tell your physician, who will help you weigh the benefits of the drug for you against possible risks to your baby. As you improve on PRO-LEVOCARB, you may increase your physical activity gradually and with caution related to any other medical conditions you may have.

PRO-LEVOCARB should not be given to children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Your physician or pharmacist has a more complete list of medicines to avoid while taking PRO-LEVOCARB. Tell your physician about all medicines you are taking or plan to take, including those obtained without a prescription.

Although PRO-LEVOCARB can generally be given with other medicines, there are exceptions. Your physician may warn against use with certain medications used to treat psychiatric conditions or mental depression, tuberculosis, high blood pressure, muscle spasms or convulsions.

It is particularly important to tell your physician if you are taking:

- antihypertensive drugs (used to treat elevated blood pressure)
- some medications used to treat psychiatric conditions or mental depression (including phenothiazines, butyrophenones, risperidone, phenytoin, papaverine, selegiline, tricyclic antidepressants and monoamine oxidase inhibitors) tetrabenazine (medication used to treat conditions related to involuntary movements such as Huntingtons Disease)
- phenytoin (anti-epileptic medication)
- papaverine (medication for intestinal spasms)
- isoniazid (medication to treat tuberculosis)
- metoclopramide (for nausea and vomiting)
- iron salts (such as multivitamin tablets) which may reduce the amount of carbidopa and/or levodopa available to the body

A change in diet to foods that are high in protein (such as meat, fish, dairy products, seeds and nuts) may delay the absorption of levodopa and PRO-LEVOCARB may not work as well as it should.

PROPER USE OF THIS MEDICATION

Usual dose:

The dosage of PRO-LEVOCARB is variable and your physician will adjust it according to the severity of your disease and your response to treatment.

PRO-LEVOCARB is an immediate-release formulation of levodopa-carbidopa that is designed to begin release of ingredients within 30 minutes. For best results take PRO-LEVOCARB every day. It is important to carefully follow your physician’s advice on how much PRO-LEVOCARB to take and how often to take it. Promptly inform your physician of any change in your condition such as nausea or abnormal movements, as this may require an adjustment in your prescription. Do not change the dose regimen prescribed by your physician and do not add any additional antiparkinson medications, including other levodopa-carbidopa preparations,

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without first consulting your physician.

Do not stop taking this medicine abruptly or lower the dosage without checking with your physician. If you suddenly stop or reduce your dosage you may experience the following symptoms: stiff muscles, high temperature (fever) and mental changes.

Overdose:

In case of an overdose, contact your physician immediately so that medical attention may be given promptly.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Missed Dose:

Try to take PRO-LEVOCARB as prescribed. However, if you have missed a dose, take it as soon as you remember. If it is almost time to take your next tablet, do not take the missed tablet, but resume your normal schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

PRO-LEVOCARB is generally well tolerated. Like any other medicine, however, PRO-LEVOCARB may have unintended or undesirable effects, so called side-effects.

Very rare but serious side effects that have been reported include sudden sleep onset episodes (see WARNINGS AND PRECAUTIONS).

Certain side effects that have been reported with PRO-LEVOCARB may affect some patients' ability to drive or operate machinery.

PRO-LEVOCARB CR can cause somnolence (excessive drowsiness) and sudden sleep onset episodes. Therefore you must refrain from driving or engaging in activities where impaired alertness may put yourself or others at risk of injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved (see WARNINGS AND PRECAUTIONS).

The most frequent side effects are: abnormal movements including twitching or spasms (which may or may not resemble your Parkinson's symptoms), and nausea.

Other possible side effects include: mental changes, dream abnormalities, hair loss, diarrhea, dizziness,

vomiting, loss of appetite, and slow movement (See WARNINGS AND PRECAUTIONS). Occasionally, dark colour (red, brown or black) may appear in your saliva, urine or sweat after you take PRO-LEVOCARB.

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms / Effects		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only of severe	In all cases	
Most Common	Abnormal involuntary movements, such as spasms or twitching		√	
Common	Hallucinations (seeing or hearing things that are not there)		√	
Rare	Allergic reactions [red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing or swallowing]			√
	Excessive sleepiness; Falling asleep without warning	√		
	Impulse control symptoms (inability to resist the impulse to perform an action that could be harmful) such as compulsive gambling, increased sexual urges	√		

	and/or behaviours, uncontrollable excessive shopping or spending, binge/compulsive eating, and/or other urges.			
	Changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes (melanoma)		√	
	Uneven (irregular) heart beat or palpitations		√	
	Feeling of lightheadedness as when standing quickly		√	

This is not a complete list of side effects. For any unexpected effects while taking ^{Pr} PRO-LEVOCARB CR, contact your doctor or pharmacist.

HOW TO STORE IT

Store your tablets in a tightly closed container at room temperature (15° - 30°C). Protect from light and moisture.

Keep all medicines out of the reach of children.

Do not use outdated medicine.

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REPORTING SUSPECTED SIDE EFFECTS

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

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 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
Address Locator: 0701C
Ottawa, ON K1A 0K9

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

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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