PRODUCT MONOGRAPH

PrPROLOPA®

levodopa and benserazide capsules

50 mg - 12.5 mg, 100 mg - 25 mg, 200 mg - 50mg

Pharmaceutical standard: professed

Antiparkinson Agent

Hoffmann-La Roche Limited
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levodopa and benserazide capsules

Read this carefully before you start taking PROLOPA and each time you get a refill. This leaflet is a summary and will not tell you everything about PROLOPA. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about PROLOPA.

ABOUT THIS MEDICATION

What the medication is used for:
PROLOPA belongs to a group of medicines called antiparkinson agents which are used to treat the signs and symptoms of Parkinson's disease. Signs and symptoms of Parkinson's disease include: shaking (tremor), slowness in performing activities of daily living (bradykinesia), muscle stiffness (rigidity) and mood changes (depression).

What it does:
The symptoms of Parkinson's disease are caused by a deficiency of a natural substance (dopamine) in the part of the brain affected by Parkinson's disease. PROLOPA helps to replace this substance.

When it should not be used:
Do not take PROLOPA if you:

- have had an allergic reaction to levodopa, benserazide or any of the non-medicinal ingredients in the formulation
- have been told that you should not take sympathomimetic drugs such as , isoproterenol, amphetamine, epinephrine, or cough and cold medications containing drugs related to epinephrine
- have taken a monoamine oxidase inhibitor medicine within the last 2 weeks
- have untreated heart, liver, kidney, lung, blood or hormonal disease
- have glaucoma
- are being treated for severe mental problems
- are under the age of 25
- are pregnant or of childbearing potential in the absence of adequate contraception

What the medicinal ingredient is:
levodopa and benserazide

What the non-medicinal ingredients are:
gelatin, indigotine, iron oxide, magnesium stearate, mannitol (50 mg - 12.5 mg capsule only), microcrystalline cellulose, povidone, talc, titanium dioxide

What dosage forms it comes in:
PROLOPA (levodopa and benserazide) is available as:

50 mg - 12.5 mg capsules (light grey and blue; 50 mg levodopa and 12.5 mg benserazide)

100 mg - 25 mg capsules (blue and pale pink; 100 mg levodopa and 25 mg benserazide

200 mg - 50 mg capsules (blue and caramel-color; 200 mg levodopa and 50 mg benserazide)

WARNINGS AND PRECAUTIONS

Serious 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 PROLOPA. During treatment with PROLOPA 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 PROLOPA should have periodic skin examinations.

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

- have or have had any other health problems including: convulsions, diabetes, stomach ulcers, lung, liver, kidney or hormonal problems, depression or other mental disturbances, osteoporosis, clots in your veins, irregular heart rhythm or history of heart attack, glaucoma, skin cancer or suspicious skin lesions
- drive or operate machinery
- are pregnant or plan to become pregnant
- are breastfeeding or wish to breastfeed
- are allergic to any other medicines, foods, dyes or preservatives
- are going to have an operation that requires general anesthesia (see Interactions with this Medication)

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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PROLOPA include:

- sympathomimetic- drugs, such as cough and cold medications containing epinephrine, isoproterenol or amphetamine
- blood pressure lowering medications
- other antiparkinsonian medications (e.g. amantadine, bromocriptine, and selegiline)

- some medications used to treat mental problems
- general anesthetics with halothane. If you know you are going to have an operation, that requires this type of anesthesia, you should stop PROLOPA 12-48 hours beforehand.
- iron tablets or multivitamin tablets containing iron
- metoclopramide
- papaverine
- isoniazid
- phenytoin
- domperidone
- opioids

Protein-rich diets (for example, a lot of meat, poultry or fish) may reduce the beneficial effects of PROLOPA.

PROPER USE OF THIS MEDICATION

The amount of PROLOPA your doctor prescribes will depend on your individual symptoms and your response to treatment. When you first start taking PROLOPA the amount you take will be increased gradually. The amount has to be carefully adjusted for each person as your Parkinson's symptoms will not be controlled if you take too little PROLOPA and if you take too much PROLOPA, you may experience unwanted side effects. It may be several weeks before the best dose for you is reached.

Levodopa should be discontinued for at least twelve (12) hours before initiating therapy with PROLOPA.

You should swallow the capsules whole, with water. Do not open capsules or dissolve in liquid.

PROLOPA can cause digestive problems. In order to decrease the likelihood of you getting these, take PROLOPA with a snack that has little or no protein, such as fruit, applesauce or biscuits. Taking PROLOPA with a snack or meal that has protein may reduce its effectiveness.

Usual adult dose:
Your doctor will decide how many PROLOPA capsules you will need to take each day.

You should always follow your doctor's instructions about how many PROLOPA capsules to take each day and when you should take them.

Keep taking your medication, as instructed, until your doctor tells you to stop.

Overdose:

If you think you have taken too much PROLOPA contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed a dose, take it as soon as you remember. If it is almost time to take your next capsule, do not take the missed capsule, but carry on with your regular schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications PROLOPA capsules 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.

- The most common serious side effects are abnormal involuntary movements such as twitching or spasms which may or may not resemble your Parkinson's symptoms. It may help if the daily dose is reduced or smaller doses are taken more frequently.
- At the beginning of treatment, nausea, vomiting or diarrhea can occur.
- Psychiatric problems are common in people with Parkinson's disease and may occur during treatment with PROLOPA. These may include depression, confusion, anxiety, agitation, hallucinations, nightmares, and other mental changes.
- Other possible side effects include: changes in heart rhythm, changes in blood pressure, faintness, sleepiness, sweating, rash, itching, dark color in your sweat or urine, staining of your body fluids or tissues (saliva, tongue, teeth, tissue in your mouth). Very rarely changes in behaviour, such as compulsive gambling or change in sexual desire, may occur.
- Against the advice of their doctor, patients sometimes increase the quantity of drug they take well beyond what they need as treatment for their symptoms.
- PROLOPA can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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 seek immediate medical help
		Only if severe	In all cases	
Common	Abnormal involuntary movements, such as spasms or twitching		✓	
	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]			✓
	Uneven (irregular) heart beat or palpitations		✓	
	Feeling of light headedness when standing quickly		✓	
Very rare	Excessive sleepiness, Falling asleep without warning		✓	
	Impulse control symptoms, such as increased sexual urges and/or behaviors compulsive gambling, uncontrollable excessive shopping or spending, binge/ compulsive eating, and/or other urges		✓	
	Taking doses in excess of what is recommended or required to control symptoms		✓	

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

HOW TO STORE IT

Keep PROLOPA in a tightly closed, light-resistant container. Store at 15-30°C.

Keep out of reach and sight of children.

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: 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**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    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 the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388 (Drug Information).

This leaflet was prepared by Hoffmann-La Roche Limited

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