

LEVODOPA AND BENSERAZIDE (Systemic)*

Some commonly used brand names are:

In Canada—

- Prolopa[reg]
- * Not commercially available in the U.S.

Category

Antidyskinetic

Description

Levodopa and Benserazide (lee-voe-DOE-pa AND ben-sir-A-zide) is used to treat Parkinson's disease, sometimes called shaking palsy or paralysis agitans. This medicine works to increase and extend the effects of levodopa, and may help to slow the progress of Parkinson's disease.

This medicine is available only with your doctor's prescription, in the following dosage forms:

Oral

• Capsules (Canada)

Importance of Diet

Since protein may interfere with the body's response to levodopa, high protein diets should be avoided. Intake of normal amounts of protein should be spaced equally throughout the day, or taken as directed by your doctor.

Before Using This Medicine

Pregnancy—Studies have not been done in pregnant women. However, studies in animals have shown that levodopa affects the baby's growth both before and after birth if given during pregnancy.

Breast-feeding—Levodopa and benserazide passes into breast milk and may cause unwanted side effects in the nursing baby. Also, levodopa may reduce the flow of breast milk.

Children—Studies on this medicine have been done only in adult patients, and there is no specific information comparing use of levodopa or benserazide in children with use in other age groups.

Other medicines—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your

doctor may want to change the dose, or other precautions may be necessary. When you are taking levodopa and benserazide, it is especially important that your doctor and pharmacist know if you are taking any of the following:

- Anesthetics
- Antihypertensive agents—May decrease blood pressure even more as seen with levodopa therapy
- Monoamine oxidase (MAO) inhibitor activity (isocarboxazid [e.g., Marplan], phenelzine [e.g., Nardil], procarbazine [e.g., Matulane], selegiline [e.g., Eldepryl], tranylcypromine [e.g., Parnate])
 —Taking levodopa while you are taking or within 2 weeks of taking monoamine oxidase (MAO) inhibitors may cause sudden extremely high blood pressure
- · Reserpine or
- · Phenothiazines or
- Tricyclic antidepressants—Levodopa and benserazide therapy may make the patients depression worse or increase the risk of suicidal tendencies

Other medical problems—The presence of other medical problems may affect the use of levodopa and benserazide. Make sure you tell your doctor if you have any other medical problems, especially:

- · Blood disorder or
- History of heart attack or arrhythmias or
- Kidney disease or
- · Liver disease or
- Melanoma (a type of skin cancer) (or history of) or
- Mental illness—Levodopa may make the condition worse
- Seizure disorders, such as epilepsy (history of)—The risk of seizures may be increased
- Stomach ulcer (history of)—The ulcer may occur again

Proper Use of This Medicine

At first, levodopa and benserazide may be taken with a meal or a snack, so that any effects like stomach upset will be lessened. Later, as your body becomes accustomed to the medicine, it should be taken on an empty stomach so that it works better. Be sure to talk to your doctor about the best time for you to take this medicine.

The levodopa and benserazide capsules should be swallowed whole and not opened or dissolved in liquid.

Take this medicine only as directed. Do not take more or less of it, and do not take it more often than your doctor ordered.

Some people must take this medicine for several weeks or months before full benefit is received. *Do not stop taking it even if you do not think it is working*. Instead, check with your doctor.

Dosing—The dose of levodopa or carbidopa and levodopa combination will be different for different patients. *Follow your doctor's orders or the directions on the label*. The following information includes only the average doses of levodopa or carbidopa and levodopa combination. *If your dose is different, do not change it* unless your doctor tells you to do so.

The number of tablets that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on your special needs.

For levodopa and benserazide

- For Parkinson's disease—start of therapy:
 - For oral dosage form (capsules):
 - Adults—At first, 1 capsule of Prolopa[reg] 100-25 (levodopa 100 milligrams (mg) and benserazide 25 mg) twice daily. Your doctor may increase your dose if needed. However, the dose is usually not more than 4 to 8 capsules of Prolopa[reg] 100-25 per day (400 to 800 mg levodopa) divided into 4 to 6 doses. If you are already on levodopa, the doctor will start you on a lower dose of Prolopa[reg]. After time, the previous levodopa therapy will be replaced with the levodopa and benserazide combination.
 - Children up to 18 years of age—Use and dose must be determined by your doctor.
- For Parkinson's disease—maintain therapy:
 - For oral dosage form (capsules):
 - Adults—After several weeks, the doctor will determine your optimal dose of levodopa and benserazide. Your doctor may then switch you to Prolopa[reg] 200-50 (levodopa 200 milligrams (mg) and benserazide 50 mg) to make it more convenient to match your optimal dose. Some patients may require frequent dosing in which case your doctor may use Prolopa[reg] 50-12.5 (50 mg levodopa and 12.5 mg benserazide). Frequent dosing may be used to maximize your dose and minimize any side effects. During the first year of therapy, the total daily dose of levodopa should not exceed 1000 to 1200 mg.
 - Children up to 18 years of age—Use and dose must be determined by your doctor.

Missed dose—If you miss a dose of this medicine, take it as soon as possible. However, if your next scheduled dose is within 2 hours, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage—To store this medicine:

- · Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine

Before having any kind of surgery (including dental surgery) or emergency treatment, tell the medical doctor or dentist in charge that you are taking this medicine.

This medicine may cause some people to become dizzy, confused, or have blurred or double vision. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert or not able to see well.

Dizziness, light-headedness, or fainting may occur, especially when you get up from a lying or sitting position . Getting up slowly may help. If the problem continues or gets worse, check with your doctor.

As your condition improves and your body movements become easier, *be careful not to overdo physical activities. Injuries resulting from falls may occur*. Physical activities must be increased gradually to allow your body to adjust to changing balance, circulation, and coordination. *This is especially important in the elderly*.

Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

Absence of or decrease in body movement; increased blinking or twitching of eyelids; involuntary movements of the limbs and facial muscles; disorder marked especially by sadness, inactivity, difficulty with thinking and concentration, or feelings of dejection and hopelessness; twitching, twisting, uncontrolled repetitive movements of tongue, lips, face, arms, or legs; inability to move eyes increased blinking or spasms; sudden

freezing, hypotonia and postural instability; , muscle twitching; fearfulness, suspiciousness, or other mental changes; agitation, delusions, hallucinations

Less common

A condition where you have a constricted pupil, drooping of the upper eyelid, an absence of sweating over the affected side of the face; a twisting of the neck to one side; bleeding gums; blurred vision; burning while urinating; change in the color of urine or blood in urine; chest pain or tightness; chills, swollen neck, and sore throat sometimes with local ulceration; color changes in skin color; confusion, dizziness, faintness, or light-headedness when getting up from lying or sitting position; difficulty in swallowing; dizziness; fainting; fast, slow, or irregular heartbeat; flushing; inability to move eyes; nosebleeds; pain or tenderness swelling of foot or leg; pounding feeling in the ears; seizures; severe stomach pain; stomach pain or ulcer; swollen glands; unusual bleeding or bruising; unusual tiredness or weakness; vomiting of blood or material that looks like coffee grounds

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome.

Less common

Absence of or decrease in body movement loss or impairment of voluntary activity; belching; bitter taste; bizarre breathing; bloating or swelling of face, hands, lower legs, and/or feet; blurred vision; burning sensation of the tongue; change in urinary frequency; change in walking and balance; clenching, gnashing, or grinding teeth; constipation; cough; dark sweat; dark urine; decrease in urine production; diarrhea; dilated pupils; double vision; dry mouth; excessive watering of mouth; false or unusual sense of well-being; fatigue and malaise; fever; general feeling of discomfort or illness; hair loss; hallucinations and delusion; headache; hiccups; hoarseness; impairment in ability to think; increased hand tremor; increased in sexual ability or desire; loss of bladder control; low back pain; mood or mental changes; muscle or bone pain; muscle spasm and twitching; nervousness, restlessness, irritability, insomnia; passing gas; rash; shakiness and unsteady walk, clumsiness, trembling problems with muscle control or coordination; stomach problems; tightness of the mouth, lips or tongue; trouble sleeping; unusual tiredness or weakness

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.